The Notes may be redeemed at the Company's option at any time at 100% of the principal amount plus accrued and unpaid interest, and, until a specified period before maturity, a specified make-whole amount. The Notes contain a change-of-control provision that, under certain circumstances, may require the Company to offer to repurchase the Notes at a price equal to 101% of the principal amount plus accrued and unpaid interest.

The Notes also contain certain limitations on the Company's ability to incur liens and enter into sale and leaseback transactions, as well as customary events of default.

10. Commitments and Contingencies

See Note 15 for disclosures related to legal contingencies.

a. Leases

We conduct certain of our research, development, and administrative activities at leased facilities. We also lease certain warehouses and vehicles. As described in Note 1, during the first quarter of 2019, we adopted ASC 842, *Leases*.

Operating leases

Amounts recognized in our Consolidated Balance Sheets and Statements of Operations included in this report associated with operating leases were not material. Operating lease right-of-use assets are included within Other noncurrent assets, and lease liabilities are included in Accrued expenses and other current liabilities and Other noncurrent liabilities.

Finance leases

In March 2017, we entered into a Participation Agreement with BA Leasing BSC, LLC, an affiliate of Banc of America Leasing & Capital LLC ("BAL"), as lessor, and a syndicate of lenders (collectively, the "Lease Participants"). In March 2017, we also entered into a Lease and Remedies Agreement with BAL, pursuant to which we have leased laboratory and office facilities in Tarrytown, New York (the "Facility") for a five-year term ending in March 2022. The Participation Agreement, the Lease and Remedies Agreement, and certain other related agreements were amended and restated in May 2019, among other things, to revise certain covenants, representations and warranties, and events of default to be substantially similar to those set forth in the agreement governing the Company's revolving credit facility (as so amended and restated, the "Participation Agreement" and the "Lease," respectively). The Lease requires us to pay all maintenance, insurance, taxes, and other costs arising out of the use of the Facility. We are also required to make monthly payments of basic rent during the term of the Lease in an amount equal to a variable rate per annum based on the one-month LIBOR, plus an applicable margin that varies with our debt rating and total leverage ratio. The Participation Agreement and the Lease include an option for us to elect to extend the maturity date of the Participation Agreement and the term of the Lease for an additional five-year period, subject to the consent of all the Lease Participants and certain other conditions. We also have the option prior to the end of the term of the Lease to (a) purchase the Facility by paying an amount equal to the outstanding principal amount of the Lease Participants' advances under the Participation Agreement, all accrued and unpaid interest and yield thereon, and all other outstanding amounts under the Participation Agreement, the Lease, and certain related documents or (b) sell the Facility to a third party on behalf of BAL. The advances under the Participation Agreement mature, and all amounts outstanding thereunder will become due and payable in full, at the end of the term of the Lease.

Prior to January 1, 2019, for certain of the premises under the Lease we were deemed, in substance, to be the owner of the buildings (collectively, the "Build-to-Suit Buildings"). Upon the adoption of ASC 842, the classification of the Build-to-Suit Buildings, for which the construction period had been completed, was reassessed and, consequently, they were derecognized and recognized as a finance lease. These premises, along with the other premises under the Lease, are classified as a finance lease as we have the option to purchase the Facility under terms that make it reasonably certain to be exercised.

The agreements governing the Lease financing contain financial and operating covenants. The Company was in compliance with all such covenants as of December 31, 2020.

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Amounts recognized in the Consolidated Balance Sheet related to the Lease are included in the table below. Other than the Lease described above, we had no leases accounted for as finance leases as of December 31, 2020 and 2019.

	Classification	As of December 31, 2020	As of December 31, 2019
Finance lease right-of-use assets	Property, plant, and equipment, net[(1)]	$ 645.7	$ 660.1
Finance lease liabilities	Finance lease liabilities (noncurrent)	$ 717.2	$ 713.9

[(1)] Finance lease right-of-use assets are recorded net of accumulated amortization of $90.5 million and $76.1 million as of December 31, 2020 and 2019, respectively.

Finance lease costs consist of the following:

	Year Ended December 31, 2020	Year Ended December 31, 2019
Amortization of right-of-use assets	$ 14.4	$ 14.4
Interest on lease liabilities	15.7	27.6
	$ 30.1	$ 42.0

Other information related to our finance lease includes the following:

	As of December 31, 2020	As of December 31, 2019
Remaining lease term (in years)	1.17	2.17
Discount rate	1.66%	3.05%

Supplemental information

The following is a maturity analysis of our finance lease liabilities:

	As of December 31, 2020
2021	$ 12.1
2022	723.1
2023	—
2024	—
2025	—
Thereafter	—
Total undiscounted lease payments	735.2
Imputed interest	(15.1)
Debt financing costs	(2.9)
Total lease liabilities	$ 717.2

(Unless otherwise noted, dollars in millions, except per share data)

b. Research Collaboration and Licensing Agreements

As part of our research and development efforts, we enter into research collaboration and licensing agreements with other companies, universities, and other organizations. These agreements contain varying terms and provisions which include fees to be paid by the Company, services to be provided, and license rights to certain proprietary technology developed under the agreements. Some of these agreements may require the Company to pay additional amounts upon the achievement of various development and commercial milestones, contingent upon the occurrence of various future events. Additionally, we have in-licensed patent and/or technology pursuant to agreements which contain provisions that require the Company to pay royalties, as defined, at rates that range from 0.5% to 11.5%, in the event the Company sells or licenses any proprietary products developed under the respective agreements. The Company also has contingent reimbursement obligations to its collaborators Sanofi and Bayer out of the respective collaboration's profits, if they are sufficient for that purpose. See Note 3 for a more detailed description of collaboration, license, and other agreements.

For the years ended December 31, 2020, 2019, and 2018, the Company recorded royalty expense (net of reimbursements from collaborators, as applicable) in Cost of goods sold and Cost of collaboration and contract manufacturing of $56.5 million, $47.0 million, and $30.1 million, respectively, based on product sales of commercial products under various licensing agreements.

11. Stockholders' Equity

The Company's Restated Certificate of Incorporation, as amended, provides for the issuance of up to 40 million shares of Class A Stock, par value $0.001 per share, and 320 million shares of Common Stock, par value $0.001 per share. Shares of Class A Stock are convertible, at any time, at the option of the holder into shares of Common Stock on a share-for-share basis. Holders of Class A Stock have rights and privileges identical to Common Stockholders except that each share of Class A is entitled to ten votes per share, while each share of Common Stock is entitled to one vote per share. Class A Stock may only be transferred to specified Permitted Transferees, as defined. Under the Company's Restated Certificate of Incorporation, the Company's board of directors is authorized to issue up to 30 million shares of Preferred Stock, in series, with rights, privileges, and qualifications of each series determined by the board of directors.

Share Repurchase Program

In November 2019, our board of directors authorized a share repurchase program to repurchase up to $1.0 billion of our Common Stock. The share repurchase program permitted the Company to effect repurchases through a variety of methods, including open-market transactions (including pursuant to a trading plan adopted in accordance with Rule 10b5-1 of the Exchange Act), privately negotiated transactions, accelerated share repurchases, block trades, and other transactions in compliance with Rule 10b-18 of the Exchange Act. As of December 31, 2020, the Company had repurchased the entire $1.0 billion it was authorized to repurchase under the program.

The table below summarizes the shares of our Common Stock we repurchased under the program and the cost of the shares received, which were recorded as Treasury Stock.

	Year Ended December 31,	
	2020	2019
Number of shares repurchased	1,605,582	722,596
Total cost of shares received	$ 746.0	$ 254.0

In January 2021, our board of directors authorized a new share repurchase program to repurchase up to $1.5 billion of our Common Stock. The share repurchase program was approved under terms substantially similar to the November 2019 share repurchase program described above.

Arrangements with Sanofi

In 2007, Sanofi purchased 12 million newly issued, unregistered shares of the Company's Common Stock. As a condition to the closing of this transaction, Sanofi entered into an investor agreement, as amended and restated, with the Company. Under the amended and restated investor agreement, Sanofi agreed not to dispose of any shares of the Company's Common Stock beneficially owned by Sanofi from time to time until December 20, 2020 (subject to the limited waiver described below).

Further, pursuant to the amended and restated investor agreement, Sanofi is bound by certain "standstill" provisions, which contractually prohibit Sanofi from seeking to directly or indirectly exert control of the Company or acquiring more than 30% of

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the outstanding shares of the Company's Class A Stock and Common Stock (taken together). This prohibition will remain in place until the earliest of (i) the later of the fifth anniversaries of the expiration or earlier termination of the Company's License and Collaboration Agreement with Sanofi and the Company's ZALTRAP Agreement with Sanofi, each as amended, and (ii) other specified events. Sanofi has also agreed to vote as recommended by the Company's board of directors, except that it may elect to vote proportionally with the votes cast by all of the Company's other shareholders with respect to certain change-of-control transactions, and to vote in its sole discretion with respect to liquidation or dissolution, stock issuances equal to or exceeding 20% of the outstanding shares or voting rights of the Company's Class A Stock and Common Stock (taken together), and new equity compensation plans or amendments if not materially consistent with the Company's historical equity compensation practices. The rights and restrictions under the investor agreement are subject to termination upon the occurrence of certain events and have been amended in connection with the Secondary Offering and the Stock Purchase (each as defined below).

As described in Note 3, effective January 2018, we and Sanofi entered into a Letter Agreement, which, among other things, amended certain provisions of the amended and restated investor agreement. Pursuant to the Letter Agreement, we granted Sanofi a limited waiver of the lock-up obligations under the investor agreement in order to allow Sanofi to satisfy in whole or in part its funding obligations with respect to Libtayo development costs and/or Dupilumab/Itepekimab Eligible Investments for quarterly periods ending on September 30, 2020 by selling our Common Stock directly or indirectly owned by Sanofi. The table below summarizes the shares of our Common Stock Sanofi elected to sell, and we elected to purchase, to satisfy Sanofi's funding obligations and the cost of the shares received, which were recorded as Treasury Stock.

	As of December 31,		
	2020	2019	2018
Libtayo:			
Number of shares purchased (by issuing a credit towards the amount owed by Sanofi)	77,677	210,733	215,387
Total cost of shares received	$ 41.7	$ 73.3	$ 75.8
Dupilumab/Itepekimab:			
Number of shares purchased (in cash)	171,471	93,286	10,766
Total cost of shares received	$ 93.3	$ 29.4	$ 4.4

In May 2020, a secondary offering of 13,014,646 shares of our Common Stock (the "Secondary Offering") held by Sanofi was completed. In connection with the Secondary Offering, we also purchased 9,806,805 shares directly from Sanofi for an aggregate purchase amount of $5 billion (the "Stock Purchase"). See Note 9 for additional information. As a result of the Secondary Offering and the Stock Purchase, Sanofi disposed of all of its shares of our Common Stock, other than 400,000 shares that it retained as of the closing of the Secondary Offering and the Stock Purchase (a portion of which Sanofi has used for the funding of certain development costs described above).

In May 2020, the Company entered into an amendment to the amended and restated investor agreement, which provides, among other things, that following the Secondary Offering and Share Purchase, (1) the “standstill” provisions, which contractually prohibit Sanofi from seeking to directly or indirectly exert control of the Company, continue to apply pursuant to their terms; (2) the voting commitments contained in the investor agreement continue to apply to the shares of Common Stock held by Sanofi and its affiliates following the secondary offering and stock repurchase, for so long as such shares are held by them; and (3) the lock-up restrictions in the investor agreement continued to apply to the shares of Common Stock held by Sanofi following the Secondary Offering and Stock Purchase until December 20, 2020 (except those shares which could be used to satisfy certain funding obligations of Sanofi).

Arrangements with Other Collaborators

In connection with the Company's license and collaboration agreements with Bayer for the joint development and commercialization outside the United States of antibody product candidates to PDGFR-beta and Ang2, Bayer is bound by certain "standstill" provisions, which contractually prohibit Bayer from seeking to influence the control of the Company or acquiring more than 20% of the Company's outstanding shares of Class A Stock and Common Stock (taken together). With respect to each of these agreements, this prohibition will remain in place until the earliest of (i) the fifth anniversary of the

termination of the agreement (which, in the case of the PDGFR-beta license and collaboration agreement, occurred on July 31, 2017, and, in the case of the Ang2 agreement, occurred on November 1, 2018) or (ii) other specified events.

Further, pursuant to the 2016 Teva Collaboration Agreement, Teva and its affiliates are bound by certain "standstill" provisions, which contractually prohibit them from seeking to directly or indirectly exert control of the Company or acquiring more than 5% of the Company's Class A Stock and Common Stock (taken together). This prohibition will remain in place until the earliest of (i) the fifth anniversary of the expiration or earlier termination of the agreement or (ii) other specified events.

12. Long-Term Incentive Plans

The Company has used long-term incentive plans for the purpose of granting equity awards to employees of the Company, including officers, and nonemployees, including nonemployee members of the Company's board of directors (collectively, "Participants"). The Participants may receive awards as determined by a committee of independent members of the Company's board of directors or, to the extent authorized by such committee with respect to certain Participants, a duly authorized employee (collectively, the "Committee"). The incentive plan currently used by the Company is the Second Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (the "Second Amended and Restated 2014 Incentive Plan"). It was most recently adopted and approved by the Company's shareholders in 2020, at which time the Company registered an additional 12,000,000 shares of Common Stock for issuance thereunder. As of the most recent shareholder approval date, the Second Amended and Restated 2014 Incentive Plan provided for the issuance of up to 22,269,970 shares of Common Stock in respect of awards. In addition, upon expiration, forfeiture, surrender, exchange, cancellation, or termination of any award previously granted under the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (the "Amended and Restated 2014 Incentive Plan"), the Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (the "Original 2014 Incentive Plan"), or the Second Amended and Restated 2000 Long-Term Incentive Plan (the "2000 Incentive Plan"), any shares subject to such award are added to the pool of shares available for grant under the Second Amended and Restated 2014 Incentive Plan.

The awards that may be made under the Second Amended and Restated 2014 Incentive Plan include: (a) incentive stock options and nonqualified stock options, (b) shares of restricted stock, (c) shares of phantom stock (also referred to as restricted stock units, which may be time- or performance-based), and (d) other awards. Any award granted may (but is not required to) be subject to vesting based on the attainment by the Company of performance goals pre-established by the Committee.

Stock option awards grant Participants the right to purchase shares of Common Stock at prices determined by the Committee, with exercise prices that are equal to or greater than the average of the high and low market prices of the Company's Common Stock on the date of grant (the "Market Price"). Options vest over a period of time determined by the Committee, generally on a pro rata basis over a three- to four-year period. The Committee also determines the expiration date of each option. The maximum term of options that have been awarded under the 2000 Incentive Plan, the Original 2014 Incentive Plan, the Amended and Restated 2014 Incentive Plan, and the Second Amended and Restated 2014 Incentive Plan (collectively, the "Incentive Plans") is ten years.

Restricted stock awards grant Participants shares of restricted Common Stock or allow Participants to purchase such shares at a price determined by the Committee. Such shares are nontransferable for a period determined by the Committee ("vesting period"). Should employment terminate, as specified in the Incentive Plans, except as determined by the Committee in its discretion and subject to the applicable Incentive Plan documents, the ownership of any unvested restricted stock will be transferred to the Company.

Phantom stock awards provide the Participant the right to receive Common Stock or an amount of cash based on the value of the Common Stock at a future date. The award is subject to such restrictions, if any, as the Committee may impose at the date of grant or thereafter, including a specified period of employment or the achievement of performance goals. Time-based restricted stock units and performance-based restricted stock units are each a type of phantom stock award permitted under the Second Amended and Restated 2014 Incentive Plan.

The Incentive Plans contain provisions that allow for the Committee to provide for the immediate vesting of awards upon a change in control of the Company, as defined in the Incentive Plans.

As of December 31, 2020, there were 18,916,095 shares available for future grants under the Second Amended and Restated 2014 Incentive Plan. No additional awards may be made under the 2000 Incentive Plan, the Original 2014 Incentive Plan, or the Amended and Restated 2014 Incentive Plan.

(Unless otherwise noted, dollars in millions, except per share data)

a. Stock Options

Transactions involving stock option awards during 2020 under the Company's Incentive Plans are summarized in the table below.

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Intrinsic Value
Outstanding as of December 31, 2019	28,609,277	$ 337.24		
2020: Granted	2,850,590	$ 492.60		
Forfeited	(562,629)	$ 379.02		
Expired	(56,282)	$ 473.77		
Exercised	(9,139,287)	$ 281.90		
Outstanding as of December 31, 2020	21,701,669	$ 379.51	6.34	$ 2,347.4
Vested and expected to vest as of December 31, 2020	20,764,534	$ 377.23	6.22	$ 2,294.1
Exercisable as of December 31, 2020	13,648,899	$ 357.65	4.96	$ 1,799.1

The Company satisfies stock option exercises with newly issued shares of the Company's Common Stock. The total intrinsic value of stock options exercised during 2020, 2019, and 2018 was $2.251 billion, $558.9 million, and $510.6 million, respectively. The intrinsic value represents the amount by which the market price of the underlying stock exceeds the exercise price of an option.

The table below summarizes the weighted-average exercise prices and weighted-average grant-date fair values of options issued during the years ended December 31, 2020, 2019, and 2018.

	Number of Options Granted	Weighted-Average Exercise Price	Weighted-Average Fair Value
2020:			
Exercise price equal to Market Price	2,850,590	$ 492.60	$ 126.50
2019:			
Exercise price equal to Market Price	3,271,222	$ 366.65	$ 100.80
2018:			
Exercise price equal to Market Price	4,665,320	$ 378.51	$ 114.39

For the years ended December 31, 2020, 2019, and 2018, the Company recognized $329.5 million, $422.8 million, and $421.8 million, respectively, of non-cash stock-based compensation expense related to stock option awards (net of amounts capitalized as inventory of $8.3 million, $2.4 million, and $17.1 million, respectively). As of December 31, 2020, there was $491.5 million of stock-based compensation cost related to outstanding stock options, net of estimated forfeitures, which had not yet been recognized. The Company expects to recognize this compensation cost over a weighted-average period of 1.8 years.

(Unless otherwise noted, dollars in millions, except per share data)

Fair Value Assumptions:

The following table summarizes the weighted average values of the assumptions used in computing the fair value of option grants during 2020, 2019, and 2018.

	2020	2019	2018
Expected volatility	28 %	28 %	29 %
Expected lives from grant date	5.0 years	5.0 years	4.9 years
Expected dividend yield	0 %	0 %	0 %
Risk-free interest rate	0.47 %	1.74 %	2.69 %

Expected volatility has been estimated based on actual movements in the Company's stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on the Company's historical exercise experience with previously issued employee and board of directors' option grants. The expected dividend yield is zero as the Company has never paid dividends and does not currently anticipate paying any in the foreseeable future. The risk-free interest rates are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives.

b. Restricted Stock Awards and Time-Based Restricted Stock Units

A summary of the Company's activity related to restricted stock awards and time-based restricted stock units (excluding performance-based restricted stock units, which are detailed further below) (collectively, "restricted stock") during 2020 is summarized below.

		Number of Shares/Units		Weighted-Average Grant Date Fair Value
Balance as of December 31, 2019		1,102,390	$	377.32
2020:	Granted	646,844	$	496.44
	Vested	(15,630)	$	526.62
	Forfeited/Cancelled	(46,061)	$	377.85
Balance as of December 31, 2020		1,687,543	$	421.58

The Company recognized non-cash stock-based compensation expense related to restricted stock of $102.5 million, $29.7 million, and $5.6 million in 2020, 2019, and 2018, respectively (net of amounts capitalized as inventory, which were not material for each of the three years). As of December 31, 2020, there was $425.5 million of stock-based compensation cost related to unvested restricted stock which had not yet been recognized. The Company expects to recognize this compensation cost over a weighted-average period of 2.7 years.

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c. Performance-based Restricted Stock Units

Performance-based restricted stock units ("PSUs") have been granted to certain executive officers of the Company. The PSUs will be earned based upon the achievement of predetermined, cumulative total shareholder return goals with respect to the Company's Common Stock price over a specified (generally five-year) period beginning on the grant date. The number of PSUs granted shown in the table below represents the maximum number of units that are eligible to be earned. Depending on the terms of the PSUs and the outcome of the performance goals, a recipient may ultimately earn 0% to 250% (as specified for each PSU grant) of the target number of PSUs granted. A summary of the Company's activity related to PSUs during 2020 is summarized below.

	Number of Shares/Units	Weighted-Average Grant Date Fair Value
Balance as of December 31, 2019	59,396	$ 198.10
2020: Granted	1,240,540	$ 209.59
Vested	—	—
Forfeited/Cancelled	—	—
Balance as of December 31, 2020	1,299,936	$ 209.06

The Company did not recognize non-cash stock-based compensation expense related to PSUs in 2020 (as PSUs granted in 2020 were granted on December 31, 2020 and will be expensed over the vesting period). The Company recognized non-cash stock-based compensation expense related to PSUs of $11.7 million in 2019 (net of amounts capitalized as inventory, which were not material). PSUs were not granted during 2018. As of December 31, 2020, there was $260.0 million of stock-based compensation cost related to unvested PSUs which had not yet been recognized. The Company expects to recognize this compensation cost on a straight-line basis over a period of 5.0 years.

Fair Value Assumptions:

The following table summarizes the weighted average values of the assumptions used in computing the fair value of PSUs during 2020 and 2019.

	2020	2019
Expected volatility	35%	33%
Expected dividend yield	0%	0%
Risk-free interest rate	0.36%	1.63%

13. Employee Savings Plans

The Company maintains the Regeneron Pharmaceuticals, Inc. 401(k) Savings Plan, as amended and restated (the "Savings Plan"). The terms of the Savings Plan allow U.S. employees (as defined by the Savings Plan) to contribute to the Savings Plan a percentage of their compensation. In addition, the Company may make discretionary contributions ("Contribution"), as defined, to the accounts of participants under the Savings Plan. The Company recognized $44.7 million, $38.1 million, and $27.0 million of Contribution expense in 2020, 2019, and 2018, respectively.

The Company also maintains additional employee savings plans outside of the United States, which cover eligible employees. Expenses recognized by the Company related to contributions to such plans were not material during 2020, 2019, and 2018.

(Unless otherwise noted, dollars in millions, except per share data)

14. Income Taxes

The Company is subject to U.S. federal, state, and foreign income taxes. Components of income before income taxes consist of the following:

	Year Ended December 31,		
	2020	2019	2018
United States	$ 2,442.3	$ 2,011.2	$ 2,151.7
Foreign	1,368.1	417.9	401.8
	$ 3,810.4	$ 2,429.1	$ 2,553.5

Components of income tax expense consist of the following:

	Year Ended December 31,		
	2020	2019	2018
Current:			
Federal	$ 199.0	$ 444.6	$ 223.7
State	1.2	1.9	4.8
Foreign	21.4	(2.6)	20.6
Total current tax expense	221.6	443.9	249.1
Deferred:			
Federal	109.0	(132.0)	687.6
State	(2.0)	(1.7)	(1.9)
Foreign	(31.4)	3.1	(825.7)
Total deferred tax (benefit) expense	75.6	(130.6)	(140.0)
	$ 297.2	$ 313.3	$ 109.1

A reconciliation of the U.S. statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,		
	2020	2019	2018
U.S. federal statutory tax rate	21.0 %	21.0 %	21.0 %
Stock-based compensation	(7.6)	(2.5)	(2.5)
Income tax credits	(2.8)	(4.6)	(2.6)
Taxation of non-U.S. operations	(1.8)	(1.0)	(1.9)
Sale of non-inventory related assets between foreign subsidiaries	(0.8)	—	(6.3)
Foreign-derived intangible income deduction	—	(1.6)	(1.0)
Non-deductible Branded Prescription Drug Fee	0.5	0.7	0.6
Impact of change in U.S. corporate tax rate (the Act)	—	—	(2.7)
Other permanent differences	(0.7)	0.9	(0.3)
Effective income tax rate	7.8 %	12.9 %	4.3 %

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In December 2017, the bill known as the "Tax Cuts and Jobs Act" (the "Act") was signed into law. The Act, which became effective with respect to most of its provisions as of January 1, 2018, significantly revised U.S. corporate income tax laws by, among other things, reducing the U.S. federal corporate income tax rate from 35% to 21%. As a result of the Act being signed into law, the Company recognized a provisional charge in the fourth quarter of 2017 related to the re-measurement of its U.S. net deferred tax assets at the lower enacted corporate tax rate, and, during 2018, we recorded an income tax benefit of $68.0 million as a final adjustment to the provisional amount recorded as of December 31, 2017, which was partly attributable to our election to record deferred tax assets and liabilities for expected amounts of GILTI inclusions.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities are as follows:

	As of December 31,	
	2020	2019
Deferred tax assets:		
Deferred compensation	$ 436.6	$ 519.7
Fixed assets and intangible assets	140.5	192.0
Accrued expenses	139.8	75.9
Deferred revenue	44.6	22.0
Total deferred tax assets	761.5	809.6
Valuation allowance	—	(7.0)
Deferred tax assets, net of valuation allowance	761.5	802.6
Deferred tax liabilities:		
Other	(42.8)	(11.2)
Net deferred tax assets	$ 718.7	$ 791.4

The Company's federal income tax returns for 2015 through 2019 remain open to examination by the IRS. The Company's 2015 and 2016 federal income tax returns are currently under audit by the IRS. In general, the Company's state income tax returns from 2016 to 2019 remain open to examination. The Company's Commonwealth of Pennsylvania returns for 2015 through 2019 are currently under audit by the Commonwealth. The United States and many states generally have statutes of limitation ranging from 3 to 5 years; however, those statutes could be extended due to the Company's tax credit carryforward position. In general, tax authorities have the ability to review income tax returns in which the statute of limitation has previously expired to adjust the tax credits generated in those years.

The following table reconciles the beginning and ending amounts of unrecognized tax benefits. The amount of unrecognized tax benefits that, if settled, would impact the effective tax rate is $267.0 million, $210.8 million, and $189.5 million as of December 31, 2020, 2019, and 2018, respectively.

	2020	2019	2018
Balance as of January 1	$ 210.8	$ 189.5	$ 146.2
Gross increases related to current year tax positions	76.6	37.9	51.4
Gross increases (decreases) related to prior year tax positions	7.2	(7.2)	5.6
Gross decreases due to settlements and lapse of statutes of limitations	(27.6)	(9.4)	(13.7)
Balance as of December 31	$ 267.0	$ 210.8	$ 189.5

In 2020, 2019 and 2018, the increases in unrecognized tax benefits primarily related to the Company's calculation of certain tax credits and other items related to the Company's international operations.

During 2020, 2019, and 2018, interest expense related to unrecognized tax benefits recorded by the Company was not material. The Company believes it is reasonably possible that its unrecognized tax benefits as of December 31, 2020 may decrease within

the next twelve months, and, as a result, positively impact our effective tax rate, as a result of expected settlement of audits and statute of limitation lapses.

15. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. Costs associated with the Company's involvement in legal proceedings are expensed as incurred. The outcome of any such proceedings, regardless of the merits, is inherently uncertain. The Company recognizes accruals for loss contingencies associated with such proceedings when it is probable that a liability will be incurred and the amount of loss can be reasonably estimated. As of December 31, 2020 and 2019, the Company had accruals for loss contingencies of $9.6 million and $100.0 million, respectively. If the Company were unable to prevail in any such proceedings, its consolidated financial position, results of operations, and future cash flows may be materially impacted.

Proceedings Relating to '287 Patent and '163 Patent

The Company is a party to patent infringement litigation initiated by the Company involving its European Patent No. 1,360,287 (the "'287 Patent") and its European Patent No. 2,264,163 (the "'163 Patent"). Each of these patents concerns genetically engineered mice capable of producing chimeric antibodies that are part human and part mouse. Chimeric antibody sequences can be used to produce high-affinity fully human monoclonal antibodies. In these proceedings, the Company claims infringement of several claims of the '287 Patent and the '163 Patent (as applicable), and seeks, among other types of relief, an injunction and an account of profits in connection with the defendants' infringing acts, which may include, among other things, the making, use, keeping, sale, or offer for sale of genetically engineered mice (or certain cells from which they are derived) that infringe one or more claims of the '287 Patent and the '163 Patent (as applicable).

On September 25, 2013, the Company commenced patent infringement litigation against Kymab Ltd in the English High Court of Justice, Chancery Division, Patents Court, in London, asserting the '287 Patent and '163 Patent. Following a trial to adjudicate the claims of infringement and counterclaims of invalidity of the '287 Patent and the '163 Patent, the court issued a final judgment on February 1, 2016, finding that the asserted claims of the '287 and '163 Patents are novel, not obvious, and infringed by Kymab's genetically engineered mice. However, the court invalidated the '287 and '163 Patents on the ground of insufficiency. On appeal, the Court of Appeal (Civil Division of England and Wales) reversed the English High Court's decision and held that the '287 Patent and '163 Patent are both valid and infringed by Kymab and subsequently issued a final order, which enjoined Kymab from infringing the '287 Patent and '163 Patent (subject to certain exceptions) and required Kymab to destroy or deliver to a third party all products and antibodies and cells engineered to produce antibodies which infringe the '287 Patent and '163 Patent (subject to certain exceptions). On June 24, 2020, the Supreme Court of the United Kingdom overturned the decision of the Court of Appeal on validity and held that the '287 and '163 Patents are each invalid on the ground of insufficiency.

Proceedings Relating to Praluent (alirocumab) Injection

As described in greater detail below, the Company is currently a party to patent infringement actions initiated by Amgen Inc. (and/or its affiliated entities) against the Company and/or Sanofi (and/or the Company's and Sanofi's respective affiliated entities) in a number of jurisdictions relating to Praluent. See Note 3 for a description of the Company's and Sanofi's arrangement regarding the costs resulting from or associated with such actions.

United States

In the United States, Amgen has asserted claims of U.S. Patent Nos. 8,829,165 (the "'165 Patent") and 8,859,741 (the "'741 Patent"), and seeks a permanent injunction to prevent the Company and the Sanofi defendants from commercial manufacturing, using, offering to sell, or selling within the United States (as well as importing into the United States) (collectively, "Commercializing") Praluent. Amgen also seeks a judgment of patent infringement of the asserted patents, monetary damages (together with interest), costs and expenses of the lawsuits, and attorneys' fees. As described in greater detail under "Second Jury Trial and Appeal" below, the parties to this litigation are currently awaiting a decision by the Federal Circuit (as defined below) on Amgen's appeal.

First Jury Trial and Appeal. The first jury trial in this litigation (the "First Trial") was held in the United States District Court for the District of Delaware (the "District Court") from March 8 to March 16, 2016. During the course of the First Trial, the District Court ruled as a matter of law in favor of Amgen that the asserted patent claims were not obvious, and in favor of the Company and the Sanofi defendants that there was no willful infringement of the asserted patent claims by the Company or the Sanofi defendants. On March 16, 2016, the jury returned a verdict in favor of Amgen in the First Trial, finding that the asserted claims of the '165 and '741 Patents were not invalid based on either a lack of written description or a lack of enablement. On October 5, 2017, the United States Court of Appeals for the Federal Circuit (the "Federal Circuit") reversed in part the District Court's decision and remanded for a new trial on the issues of written description and enablement. In addition, it affirmed the District Court's ruling that Amgen's patents were not obvious.

Second Jury Trial and Appeal. On January 3, 2019, the District Court held oral argument in the remanded proceedings on the Company and the Sanofi defendants' motion for judgment on the pleadings regarding Amgen's willful infringement claim. On January 18, 2019, the District Court entered an order (i) denying the Company and the Sanofi defendants' motion for summary judgment on validity, (ii) denying Amgen's motion for partial summary judgment on estoppel, and (iii) granting the Company and the Sanofi defendants' cross-motion for summary judgment on estoppel. On February 8, 2019, the District Court granted the Company and the Sanofi defendants' motion for judgment on the pleadings, thereby dismissing Amgen's claim of willful infringement. The second jury trial in this litigation (the "Second Trial") was held before the District Court in February 2019 to determine the validity of Amgen's asserted patent claims. On February 25, 2019, the jury returned a verdict in the Second Trial generally in favor of Amgen, finding that two claims of the '165 Patent and one claim of the '741 Patent were not invalid. The jury also found that two claims of the '165 Patent were invalid for lack of adequate written description while rejecting the lack of enablement challenges to those two claims. On August 28, 2019, the District Court ruled as a matter of law that Amgen's asserted patent claims are invalid based on lack of enablement. The District Court also conditionally denied the Company and the Sanofi defendants' motion for a new trial. On October 23, 2019, Amgen filed a notice of appeal of the District Court's decision with the Federal Circuit. An oral hearing before the Federal Circuit was held on December 9, 2020.

Injunctive Relief Proceedings. On March 18, 2019, Amgen filed a renewed motion for a permanent injunction to prohibit the Company and the Sanofi defendants from Commercializing Praluent in the United States (a "Permanent Injunction"), and an oral hearing on this motion was held in June 2019. Previously, the Federal Circuit stayed and then vacated a Permanent Injunction granted by the District Court in connection with the First Trial. On August 28, 2019, the District Court dismissed as moot Amgen's renewed motion for a Permanent Injunction.

Europe

Amgen has asserted European Patent No. 2,215,124 (the "'124 Patent"), which pertains to PCSK9 monoclonal antibodies, in the countries in Europe discussed below. As described in greater detail under "EPO Proceedings" below, in October 2020 the '124 Patent claims directed to compositions of matter and medical use were ruled invalid by the Technical Board of Appeal (the "TBA") of the European Patent Office (the "EPO"). This decision, subject to any review by the EPO Enlarged Board of Appeal, has impacted or will impact each of the infringement proceedings based on the '124 Patent discussed below.

EPO Proceedings. The '124 Patent was subject to opposition proceedings in the EPO seeking to invalidate certain of its claims, which were initiated by Sanofi on February 24, 2016 and, separately, by the Company, Sanofi, and several other opponents on November 24, 2016. On December 13, 2017, the Opposition Division of the EPO issued a preliminary, non-binding opinion (the "Preliminary Opinion") regarding the validity of the '124 Patent, indicating that it currently considers the claims of a new request filed by Amgen in response to the opposition to satisfy the requirements for patentability. An oral hearing on the oppositions against the '124 Patent was held on November 28–30, 2018, at which the Opposition Division upheld the validity of the '124 Patent's claims in amended form. The Company and Sanofi filed notices of appeal to the TBA on November 30, 2018. An oral hearing before the TBA was held on October 28–29, 2020, at which the TBA ruled that the '124 Patent claims directed to compositions of matter and medical use were invalid based on a lack of inventive step.

United Kingdom. On July 25, 2016, Amgen filed a lawsuit against Regeneron, Sanofi-Aventis Groupe S.A., Sanofi-Synthelabo Limited, Aventis Pharma Limited, Sanofi Winthrop Industrie S.A., and Sanofi-Aventis Deutschland GmbH in the English High Court of Justice, Chancery Division, Patents Court, in London, seeking a declaration of infringement of the '124 Patent by Praluent. The lawsuit also seeks a permanent injunction, damages, an accounting of profits, and costs and interest. On February 8, 2017, the court temporarily stayed this litigation on terms mutually agreed by the parties. On October 22, 2020, the court lifted the stay upon application by the Company and the Sanofi defendants, and the case will proceed in due course.

Germany. On July 25, 2016, Amgen filed a lawsuit for infringement of the '124 Patent against Regeneron, Sanofi-Aventis Groupe S.A., Sanofi Winthrop Industrie S.A., and Sanofi-Aventis Deutschland GmbH in the Regional Court of Düsseldorf,

Germany (the "Düsseldorf Regional Court"), seeking a permanent injunction, an accounting of marketing activities, a recall of Praluent and its removal from distribution channels, and damages. On November 14, 2017, the Düsseldorf Regional Court issued a decision staying the infringement proceedings until a decision of the Opposition Division of the EPO concerning the pending opposition filed by the Company, Sanofi, and several other opponents against the '124 Patent (as discussed above). Following Amgen's request to reopen the proceedings in light of the issuance of the Preliminary Opinion, the Düsseldorf Regional Court held an oral hearing on September 11, 2018 and ruled on December 10, 2018 that the infringement proceedings would be reopened. On July 11, 2019, the Düsseldorf Regional Court found that Praluent infringes the '124 Patent and granted an injunction prohibiting the Company and Sanofi's manufacture, sale, and marketing of Praluent in Germany (the "July 11 Decision"). Amgen subsequently enforced the injunction and, as a result, commercialization of Praluent in Germany was discontinued. On July 12, 2019, the Company and Sanofi appealed the July 11 Decision to the Higher Regional Court of Düsseldorf (the "Higher Regional Court"). On August 5, 2019 and October 31, 2019, the Higher Regional Court denied the Company and Sanofi's requests for a stay of preliminary enforcement of the July 11 Decision pending the appeal on the merits. On November 3, 2020, Amgen filed a motion withdrawing this lawsuit without prejudice. An oral hearing on the merits of the appeal to the Higher Regional Court was held on November 5, 2020, at which the Higher Regional Court overturned the July 11 Decision.

France. On September 26, 2016, Amgen filed a lawsuit for infringement of the '124 Patent in the Tribunal de grande instance in Paris, France against Regeneron, Sanofi-Aventis Groupe S.A., Sanofi Winthrop Industrie S.A., and Sanofi Chimie (subsequently added as a defendant). Amgen is seeking the prohibition of allegedly infringing activities with a €10,000 penalty per drug unit of Praluent produced in violation of the court order sought by Amgen; an appointment of an expert for the assessment of damages; disclosure of technical (including supply-chain) and accounting information to the expert and the court; provisional damages of €10.0 million (which would be awarded on an interim basis pending final determination); reimbursement of costs; publication of the ruling in three newspapers; and provisional enforcement of the decision to be issued, which would ensure enforcement of the decision (including any provisional damages) pending appeal. Amgen is not seeking a preliminary injunction in this proceeding at this time. On April 10, 2017, the Company and the Sanofi parties filed briefs seeking invalidation of certain of the claims of the '124 Patent, and Amgen filed a response on July 28, 2017. Oral hearing on this infringement lawsuit (originally scheduled for February 12, 2019) has yet to be rescheduled.

The Netherlands. On December 17, 2019, Amgen initiated a lawsuit alleging infringement of the Dutch designation of the '124 Patent in the District Court of The Hague in the Netherlands, against Sanofi-Aventis Netherlands B.V. and Sanofi-Aventis Groupe S.A. The Company has not been named as a defendant in this action. Amgen alleges, among other things, patent infringement based on the production, importation, and commercialization of Praluent (alirocumab) in the Netherlands. Amgen's requests are made on an accelerated basis and include, among other things, a request for a permanent injunction, damages, an order for customer information, a recall order, a destruction order, and an order for costs. A hearing has been scheduled for February 12, 2021.

Italy. On December 20, 2019, Amgen filed a lawsuit for infringement of the Italian designation of the '124 Patent in the Tribunale di Milano - Enterprise Chamber in Milan, Italy, against Sanofi-Aventis Groupe S.A., Sanofi Chimie, and Sanofi SpA. The Company has not been named as a defendant in this action. Amgen alleges that the production, importation, and commercialization of Praluent (alirocumab) in Italy infringes the '124 Patent. The writ of summons filed by Amgen seeks, among other things, a declaration of infringement, a permanent injunction, withdrawal of product from the market, and damages. On June 24, 2020, Amgen also filed a preliminary injunction motion against the Sanofi parties. On August 12, 2020, the court denied Amgen's preliminary injunction motion.

Spain. On December 20, 2019, Amgen also filed a lawsuit alleging infringement of the Spanish designation of the '124 Patent in the Juzgado de lo Mercantil No. 5 (Commercial Court) in Barcelona, Spain, against Sanofi-Aventis, S.A. The Company was not named as a defendant in this action. Amgen alleged, among other things, patent infringement based on the manufacture, offering for sale, introduction into the market, use, and importation or possession of Praluent (alirocumab) in Spain. Amgen sought, among other things, a permanent injunction, withdrawal of Praluent from the market, seizure and destruction of Praluent from the market and in storage, and damages in the form of lost profits and costs and expenses. On May 12, 2020, the court stayed this lawsuit until October 30, 2020 on terms mutually agreed by the parties. On October 30, 2020, the stay was automatically lifted. On November 2, 2020, Amgen filed a motion withdrawing this lawsuit; and, on February 1, 2021, the lawsuit was dismissed.

Other

Japan. On May 19, 2017, Amgen filed a lawsuit for infringement of Amgen's Japanese Patent Nos. 5,906,333 (the "'333 Patent") and 5,705,288 (the "'288 Patent") in the Tokyo District Court Civil Division (the "Tokyo District Court") against Sanofi K.K. Amgen's complaint alleges that manufacturing, selling or otherwise transferring, and offering to sell or otherwise transfer Praluent (alirocumab) in Japan (as well as importing Praluent (alirocumab) into Japan) infringe the '333 and '288 Patents. The complaint further seeks a permanent injunction, disposal of product, and court costs. The Company has not been named as a defendant in this litigation. On January 17, 2019, the Tokyo District Court upheld the validity of the '333 Patent and '288 Patent and ordered a permanent injunction against Sanofi K.K. to stop manufacturing, selling or otherwise transferring, and offering to sell or otherwise transfer Praluent (alirocumab) in Japan (as well as importing Praluent (alirocumab) into Japan) and to dispose of all product. However, the Tokyo District Court stayed the enforcement of such injunction pending appeal to the Intellectual Property High Court of Japan (the "IPHC"). On January 30, 2019, Sanofi K.K. appealed the Tokyo District Court's decision in the infringement proceedings to the IPHC. Following an oral hearing on October 30, 2019, the IPHC affirmed the Tokyo District Court's decision in the infringement proceedings. Sanofi K.K. appealed the IPHC's decision in the infringement proceedings to the Supreme Court of Japan on November 12, 2019. On April 24, 2020, the Supreme Court of Japan declined to hear the appeal filed by Sanofi K.K. in the infringement proceedings and the injunction issued by the Tokyo District Court became effective. Sanofi K.K. subsequently complied with the injunction and, as a result, the commercialization of Praluent in Japan has been discontinued. On March 31, 2020, Amgen filed a related lawsuit in the Tokyo District Court against Sanofi K.K. seeking damages incurred by Amgen as a result of the finding of infringement of the '333 Patent and the '288 Patent. The Company has not been named as a defendant in this damages action.

Proceedings Relating to Dupixent (dupilumab) Injection

United States

On March 20, 2017, the Company, Sanofi-Aventis U.S. LLC, and Genzyme Corporation filed a lawsuit against Amgen and Immunex Corporation, a wholly owned subsidiary of Amgen, in the United States District Court for the District of Massachusetts seeking a declaratory judgment that the Company's and the other plaintiffs' Commercializing of Dupixent does not directly or indirectly infringe U.S. Patent No. 8,679,487 (the "'487 Patent") owned by Immunex Corporation relating to antibodies that bind the human interleukin-4 receptor. On May 1, 2017, the Company and the other plaintiffs filed a notice of voluntary dismissal of this action without prejudice.

On March 23, 2017, the Company, Sanofi-Aventis U.S. LLC, and Genzyme Corporation initiated an *inter partes* review ("IPR") in the United States Patent and Trademark Office ("USPTO") seeking a declaration of invalidity of the '487 Patent. On July 28 and 31, 2017, the same parties filed two additional IPR petitions in the USPTO seeking declarations of invalidity of the '487 Patent based on different grounds (the "Additional IPR Petitions"). On October 4, 2017, the Patent Trial and Appeal Board ("PTAB") of the USPTO issued a decision on the first IPR petition and declined to institute an IPR proceeding to review the validity of the '487 Patent. On February 15, 2018, the PTAB issued two decisions instituting the Company's and Sanofi's Additional IPR Petitions on all claims of the '487 Patent for which review had been requested. Oral hearings on the Additional IPR Petitions before the PTAB were held on November 14, 2018. On February 14, 2019, the PTAB issued final written decisions on the Additional IPR Petitions, invalidating all 17 claims of the '487 Patent as obvious based on one of the Additional IPR Petitions while declining to hold the challenged claims of the '487 Patent invalid based on the other. In April 2019, the parties filed notices of appeal with the Federal Circuit appealing the PTAB's respective adverse final written decisions on the Additional IPR Petitions, and oral argument was held on August 5, 2020. On October 13, 2020, the Federal Circuit affirmed the PTAB's decision on the Additional IPR Petition that invalidated all 17 claims of the '487 Patent as obvious.

On April 5, 2017, Immunex Corporation filed a lawsuit against the Company, Sanofi, Sanofi-Aventis U.S. LLC, Genzyme Corporation, and Aventisub LLC in the United States District Court for the Central District of California seeking a judgment of patent infringement of the '487 Patent and a declaratory judgment of infringement of the '487 Patent, in each case by the Company's and the other defendants' Commercializing of Dupixent; monetary damages (together with interest); an order of willful infringement of the '487 Patent, which would allow the court in its discretion to award damages up to three times the amount assessed; costs and expenses of the lawsuit; and attorneys' fees. Immunex is not seeking an injunction in this proceeding at this time. On June 21, 2017, the court denied a motion to dismiss Immunex's complaint previously filed by the Company and the Sanofi parties. On June 28, 2017, the Company and the Sanofi parties filed an answer to Immunex's complaint and counterclaims against Immunex and Amgen (which was amended on October 31, 2017 to, among other things, add an inequitable conduct allegation), and Immunex and Amgen filed an answer to the counterclaims on July 28, 2017. A combined hearing on the construction of certain disputed claim terms of the '487 Patent and the Company and the Sanofi parties' motion for summary judgment on the issue of indefiniteness of the '487 Patent claims was held on July 12, 2018. On August 24, 2018,

the court issued an order denying this motion and construed the disputed claim terms as proposed by Amgen. On February 28, 2019, the court granted a joint stipulation by the parties to stay the litigation pending resolution of the appeals of the PTAB's final written decisions on the Additional IPR Petitions discussed above.

Europe

On September 30, 2016, Sanofi initiated a revocation proceeding in the United Kingdom to invalidate the U.K. counterpart of European Patent No. 2,292,665 (the "'665 Patent"), another patent owned by Immunex relating to antibodies that bind the human interleukin-4 receptor. At the joint request of the parties to the revocation proceeding, the U.K. Patents Court ordered on January 30, 2017 that the revocation action be stayed pending the final determination of the currently pending EPO opposition proceedings initiated by the Company and Sanofi in relation to the '665 Patent. The oral hearing before the EPO on the oppositions occurred on November 20, 2017, at which the claims of the '665 Patent were found invalid and the patent was revoked. A final written decision of revocation of the '665 Patent was issued by the EPO on January 4, 2018. Immunex filed a notice of appeal of the EPO's decision on January 31, 2018. On September 20, 2017 and September 21, 2017, respectively, the Company and Sanofi initiated opposition proceedings in the EPO against Immunex's European Patent No. 2,990,420 (the "'420 Patent"), a divisional patent of the '665 Patent (*i.e.*, a patent that shares the same priority date, disclosure, and patent term of the parent '665 Patent but contains claims to a different invention). The oral hearing before the EPO on the oppositions occurred on February 14–15, 2019, at which the '420 Patent was revoked in its entirety. Immunex filed a notice of appeal of the EPO's decision on May 31, 2019. The original patent term of the Immunex patents is set to expire in 2021.

Proceedings Relating to EYLEA (aflibercept) Injection

On January 7, 2021, Chengdu Kanghong Pharmaceutical Group Co., Ltd. filed an IPR petition in the USPTO against the Company' s U.S. Patent No. 10,464,992 (the "'992 Patent") and a post-grant review petition against the Company's U.S. Patent No. 10,828,345 (the "'345 Patent") seeking declarations of invalidity of the '992 Patent and '345 Patent.

Proceedings Relating to EYLEA (aflibercept) Injection Pre-filled Syringe

On June 19, 2020, Novartis Pharma AG, Novartis Pharmaceuticals Corporation, and Novartis Technology LLC (collectively, "Novartis") filed a complaint with the U.S. International Trade Commission (the "ITC") pursuant to Section 337 of the Tariff Act of 1930 requesting that the ITC institute an investigation relating to the importation into the United States and/or sale within the United States after importation of EYLEA pre-filled syringes ("PFS") and/or components thereof which allegedly infringe Novartis's U.S. Patent No. 9,220,631 (the "'631 Patent"). Novartis also requested a permanent limited exclusion order forbidding entry into the United States of EYLEA PFS or components thereof; a permanent cease-and-desist order from the importation, sale, offer for sale, advertising, packaging, or solicitation of any sale by the Company of EYLEA PFS or components thereof; and a bond should the Company continue to import EYLEA PFS (if found to infringe) during, if applicable, any 60-day Presidential review period (*i.e.*, the period when the President of the United States (or his designee) can disapprove any ITC decision to issue an exclusion order or cease-and-desist order). The ITC instituted the investigation on July 22, 2020 and a trial has been scheduled for April 19-23, 2021.

On June 19, 2020, Novartis also filed a patent infringement lawsuit in the U.S. District Court for the Northern District of New York asserting claims of the '631 Patent and seeking preliminary and permanent injunctions to prevent the Company from continuing to infringe the '631 Patent. Novartis also seeks a judgment of patent infringement of the '631 Patent, monetary damages (together with interest), treble damages, costs and expenses of the lawsuits, and attorneys' fees. On July 30, 2020, the court granted the Company's motion to stay these proceedings until a determination in the ITC proceedings discussed above, including any appeals therefrom, becomes final.

On July 16, 2020, the Company initiated two IPR petitions in the USPTO seeking a declaration of invalidity of the '631 Patent on two separate grounds. On January 15, 2021, the USPTO declined to institute an IPR proceeding on procedural grounds in light of the pending ITC investigation discussed above; the other IPR petition has been withdrawn.

On July 17, 2020, the Company filed an antitrust lawsuit against Novartis and Vetter Pharma International Gmbh ("Vetter") in the United States District Court for the Southern District of New York seeking a declaration that the '631 Patent is unenforceable and a judgment that the defendants' conduct violates Sections 1 and 2 of the Sherman Antitrust Act of 1890, as amended (the "Sherman Antitrust Act"). The Company is also seeking injunctive relief and treble damages. On September 4, 2020, Novartis filed, and Vetter moved to join, a motion to dismiss the complaint, to transfer the lawsuit to the Northern District of New York, or to stay the suit; and on October 19, 2020, Novartis filed, and Vetter moved to join, a second motion to dismiss the complaint on different grounds. On January 25, 2021, the Company filed an amended complaint seeking a judgment

that the Novartis's conduct violates Section 2 of the Sherman Antitrust Act based on additional grounds, as well as a judgment of tortious interference with contract.

Proceedings Related to "Most Favored Nation" Interim Final Rule

On December 11, 2020, the Company filed a lawsuit in the United States District Court for the Southern District of New York against the U.S. Department of Health and Human Services, the Secretary of HHS, the Centers for Medicare & Medicaid Services ("CMS"), and the Administrator of CMS seeking declaratory and injunctive relief related to the interim final rule with comment period entitled "Most Favored Nation (MFN) Model" issued on November 20, 2020 by HHS, acting through CMS. On the same day, the Company filed a motion for a preliminary injunction and temporary restraining order, seeking to prevent implementation of the MFN Rule. On December 22, 2020, the court heard oral argument on the Company's motion for a preliminary injunction and temporary restraining order. On December 31, 2020, the court granted the Company's motion and issued a preliminary injunction. On February 2, 2021, the government stated to the court that the Solicitor General had determined not to appeal the preliminary injunction.

Proceedings Relating to fasinumab

On May 21, 2020, the Company and Teva Pharmaceutical Industries Limited ("Teva") filed a lawsuit against Rinat Neurosciences Corp. ("Rinat"), a wholly owned subsidiary of Pfizer Inc., in the English High Court of Justice in London, seeking invalidation and revocation of Rinat's European Patent No. 2,270,048 (the "'048 Patent"), European Patent No. 1,871,416 (the "'416 Patent"), and European Patent No. 2,305,711 (the "'711 Patent"), each of which pertains to the use of NGF monoclonal antibodies to treat certain symptoms in patients suffering from osteoarthritis. On July 21, 2020, Rinat filed its defense and counterclaim seeking a declaration of infringement of the '048 Patent by fasinumab. The counterclaim also seeks a permanent injunction, damages, an accounting of profits, and costs and interest. On December 15, 2020, Rinat filed an amended defense and counterclaim seeking a declaration of infringement of the '711 Patent by fasinumab. A trial has been scheduled to commence in late November or early December 2021.

The '048 Patent is subject to opposition proceedings in the EPO, which were initiated by the Company on August 10, 2016 and two other opponents on August 11, 2016. On January 3, 2018, the Opposition Division of the EPO issued a preliminary, non-binding opinion regarding the validity of the '048 Patent, indicating that it considered the granted patent to be invalid. An oral hearing on the oppositions against the '048 Patent was held on November 29–30, 2018, at which the Opposition Division upheld the validity of the '048 Patent's claims in amended form. The Company filed a notice of appeal to the TBA of the EPO on March 7, 2019. On October 21, 2020, Teva filed a notice of intervention with the TBA to take part in the appeal proceedings as an intervener.

The '711 Patent is also subject to opposition proceedings in the EPO, which were initiated by the Company on May 1, 2018. On January 31, 2019, the Opposition Division of the EPO issued a preliminary, non-binding opinion regarding the validity of the '711 Patent, indicating that it considered the granted patent to be invalid. An oral hearing on the opposition against the '711 Patent was held on December 3, 2019, at which the Opposition Division upheld the validity of the '711 Patent's claims in amended form. The Company filed a notice of appeal to the TBA on December 20, 2019. An oral hearing before the TBA has been scheduled for July 29, 2021. On January 29, 2021, Teva filed a notice of intervention with the TBA to take part in the appeal proceedings as an intervener.

Proceedings Relating to REGEN-COV (casirivimab and imdevimab)

On October 5, 2020, Allele Biotechnology and Pharmaceuticals, Inc. ("Allele") filed a lawsuit against the Company in the United States District Court for the Southern District of New York, asserting infringement of U.S. Patent No. 10,221,221 (the "'221 Patent"). Allele seeks a judgment of patent infringement of the '221 Patent, a judgment that such infringement was willful, and an award of monetary damages (together with interest), treble damages, costs and expenses of the lawsuit, and attorneys' fees.

Department of Justice Matters

In January 2017, the Company received a subpoena from the U.S. Attorney's Office for the District of Massachusetts requesting documents relating to its support of 501(c)(3) organizations that provide financial assistance to patients; documents concerning its provision of financial assistance to patients with respect to products sold or developed by Regeneron (including EYLEA, Praluent, ARCALYST, and ZALTRAP); and certain other related documents and communications. On June 24, 2020, the U.S. Attorney's Office for the District of Massachusetts filed a civil complaint in the U.S. District Court for the District of Massachusetts alleging violations of the federal Anti-Kickback Statute, and asserting causes of action under the federal False Claims Act and state law. On August 24, 2020, the Company filed a motion to dismiss the complaint in its entirety. On December 4, 2020, the court denied the motion to dismiss.

In September 2019, the Company and Regeneron Healthcare Solutions, Inc., a wholly-owned subsidiary of the Company, each received a civil investigative demand ("CID") from the U.S. Department of Justice pursuant to the federal False Claims Act relating to remuneration paid to physicians in the form of consulting fees, advisory boards, speaker fees, and payment or reimbursement for travel and entertainment allegedly in violation of the federal Anti-Kickback Statute. The CIDs relate to EYLEA, Praluent, Dupixent, ZALTRAP, ARCALYST, and Kevzara and cover the period from January 2015 to the present. The Company is cooperating with this investigation.

Proceedings Initiated by UnitedHealthcare

On December 17, 2020, UnitedHealthcare Insurance Company and United Healthcare Services, Inc. (collectively, "UHC") filed a lawsuit against the Company in the United States District Court for the Southern District of New York alleging UHC has been damaged by the conduct alleged in the civil complaint filed by the U.S. Attorney's Office for the District of Massachusetts discussed under "Department of Justice Matters" above. UHC alleges causes of action under state law and the federal Racketeer Influenced and Corrupt Organizations Act and seeks monetary damages and equitable relief.

Shareholder Demand

On or about September 30, 2020, the Company's board of directors received a demand letter from a purported shareholder of the Company. The demand alleges that Regeneron and its shareholders have been damaged by the conduct alleged in the civil complaint filed by the U.S. Attorney's Office for the District of Massachusetts discussed under "Department of Justice Matters" above. The demand letter requests that the Company's board of directors investigate alleged breaches of fiduciary duty by its officers and directors and other alleged violations of law and corporate governance practices and procedures; bring legal action against the persons responsible for causing the alleged damages; and implement and maintain an effective system of internal controls, compliance mechanisms, and corporate governance practices and procedures. The Company's board of directors, working with outside counsel, investigated and evaluated the allegations in the demand letter and has concluded that pursuing the claims alleged in the demand would not be in the Company's best interests at this time.

16. Net Income Per Share

The calculations of basic and diluted net income per share are as follows:

	Year Ended December 31,		
	2020	**2019**	**2018**
Net income - basic and diluted	$ 3,513.2	$ 2,115.8	$ 2,444.4
(Shares in millions)			
Weighted average shares - basic	107.6	109.2	107.9
Effect of dilutive securities:			
Stock options	7.0	5.4	6.9
Restricted stock	0.5	—	—
Weighted average shares - diluted	115.1	114.6	114.8
Net income per share - basic	$ 32.65	$ 19.38	$ 22.65
Net income per share - diluted	$ 30.52	$ 18.46	$ 21.29

Shares which have been excluded from diluted per share amounts because their effect would have been antidilutive, include the following:

	Year Ended December 31,		
(Shares in millions)	2020	2019	2018
Stock options	2.7	18.4	14.9

17. Statement of Cash Flows

The following provides a reconciliation of cash, cash equivalents, and restricted cash reported within the Consolidated Balance Sheet to the total of the same such amounts shown in the Consolidated Statement of Cash Flows:

	December 31,		
	2020	2019	2018
Cash and cash equivalents	$ 2,193.7	$ 1,617.8	$ 1,467.7
Restricted cash included in Other noncurrent assets	13.6	12.5	12.5
Total cash, cash equivalents, and restricted cash shown in the Consolidated Statement of Cash Flows	$ 2,207.3	$ 1,630.3	$ 1,480.2

Restricted cash consists of amounts held by financial institutions pursuant to contractual arrangements.

Supplemental disclosure of non-cash investing and financing activities

Included in accounts payable, accrued expenses, and other liabilities as of December 31, 2020, 2019, and 2018 were $83.6 million, $133.7 million, and $54.5 million, respectively, of accrued capital expenditures.

As described in Note 11, during 2020, 2019, and 2018, we purchased (by issuing a credit towards the amount owed by Sanofi) shares of our Common Stock from Sanofi to satisfy Sanofi's funding obligation related to Libtayo development costs.

(Unless otherwise noted, dollars in millions, except per share data)

18. Unaudited Quarterly Results

Summarized quarterly financial data (unaudited) for the years ended December 31, 2020 and 2019 are set forth in the following tables. Certain revisions have been made to the previously reported 2019 quarterly amounts below in connection with changing the presentation of certain amounts earned from collaborators (see Note 1 for further details).

	First Quarter Ended March 31, 2020	Second Quarter Ended June 30, 2020[1]	Third Quarter Ended September 30, 2020	Fourth Quarter Ended December 31, 2020[2]
Revenues	$ 1,828.2	$ 1,952.0	$ 2,294.0	$ 2,422.9
Operating expenses	$ 1,128.1	$ 1,295.6	$ 1,240.9	$ 1,255.9
Net income	$ 624.6	$ 897.3	$ 842.1	$ 1,149.2
Net income per share - basic	$ 5.69	$ 8.19	$ 7.98	$ 10.90
Net income per share - diluted	$ 5.43	$ 7.61	$ 7.39	$ 10.24

	First Quarter Ended March 31, 2019	Second Quarter Ended June 30, 2019[3]	Third Quarter Ended September 30, 2019	Fourth Quarter Ended December 31, 2019
Revenues	$ 1,372.6	$ 1,577.8	$ 1,743.7	$ 1,863.5
Operating expenses	$ 892.6	$ 1,262.2	$ 1,005.2	$ 1,187.8
Net income	$ 461.1	$ 193.1	$ 669.6	$ 792.0
Net income per share - basic	$ 4.23	$ 1.77	$ 6.12	$ 7.25
Net income per share - diluted	$ 3.99	$ 1.68	$ 5.86	$ 6.93

[1] Included in operating expenses (specifically, research and development expenses) were $85.0 million in up-front payments in connection with our collaboration agreement with Intellia. See Note 3.

[2] Included in operating expenses was (i) the recognition of cumulative catch-up adjustments of $99.8 million, net, in other operating income related to updates to estimates of the total research and development costs expected to be incurred for certain collaboration agreements (see Note 3), as well as (ii) a reversal of $95.0 million within selling, general, and administrative expenses for litigation-related loss contingency accruals in connection with proceedings for Praluent outside the United States (see Note 15).

[3] Included in operating expenses (specifically, research and development expenses) was a $400.0 million up-front payment in connection with our collaboration agreement with Alnylam. See Note 3.

Regeneron Pharmaceuticals, Inc.
ID: [ ]
777 Old Saw Mill River Road
Tarrytown, New York 10591

Notice of Grant of Stock Options and Option Agreement for Time-Based Vesting Option Awards

[OPTIONEE NAME]
[OPTIONEE ADDRESS]

Option Number: [ ]
Plan: [ ]
ID: [ ]

Effective <date> (the "Grant Date") you have been granted a Non-Qualified Option to buy [ ] shares of Regeneron Pharmaceuticals, Inc. (the "Company") stock at $[ ] per share.

The total option price of the shares granted is $[ ].

Shares in each period will become fully vested on the date shown.

Shares	Vest Type	Full Vest	Expiration Date
**	On Vest Date	[__/__/__]**	[10 years from Grant Date]
**	On Vest Date	[__/__/__]**	[10 years from Grant Date]
**	On Vest Date	[__/__/__]**	[10 years from Grant Date]
**	On Vest Date	[__/__/__]**	[10 years from Grant Date]

The Non-Qualified Stock Option expires on [ ]*** (the "Expiration Date").

You and the Company agree that these options are granted under and governed by the terms and conditions of the Second Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long Term Incentive Plan, as amended from time to time, and the enclosed Option Agreement, both of which are attached and made a part of this document.

** Options for executive officers will vest in approximately equal annual 25% installments. Full Vest Dates will occur on the first, second, third and fourth anniversaries of the Grant Date.

*** Date to be 10 years from the Grant Date.

REGENERON PHARMACEUTICALS, INC.

Non-Qualified Stock Option

OPTION AGREEMENT
PURSUANT TO
THE SECOND AMENDED AND RESTATED REGENERON PHARMACEUTICALS, INC.
2014 LONG-TERM INCENTIVE PLAN

THIS AGREEMENT (this "Agreement"), made as of the date of the *Notice of Grant of Stock Options*, by and between Regeneron Pharmaceuticals, Inc., a New York corporation (the "Company"), and the employee named on the *Notice of Grant of Stock Options* (the "Grantee"). Any capitalized term used but not defined in this Agreement shall have the meaning given to such term in the Plan (as defined below).

WHEREAS, the Grantee is an employee of the Company (or a Subsidiary of the Company) and the Company desires to afford the Grantee the opportunity to acquire or enlarge the Grantee's stock ownership in the Company so that the Grantee may have a direct proprietary interest in the Company's success; and

WHEREAS, the Committee administering the Second Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (as amended from time to time, the "Plan") has granted (as of the effective date of grant specified in the *Notice of Grant of Stock Options*) to the Grantee a Stock Option to purchase the number of shares of the Company's common stock, $0.001 par value per share (the "Common Stock"), as set forth in the *Notice of Grant of Stock Options*.

NOW, THEREFORE, in consideration of the covenants and agreements herein contained, the parties agree as follows:

1. Grant of Award. Pursuant to Section 7 of the Plan, the Company grants to the Grantee, subject to the terms and conditions of the Plan and subject further to the terms and conditions set forth herein, the option (the "Option") to purchase from the Company all or any part of an aggregate of shares of Common Stock at the purchase price per share as shown on the *Notice of Grant of Stock Options*. No part of the Option granted hereby is intended to qualify as an Incentive Stock Option under Section 422 of the Internal Revenue Code of 1986, as amended (the "Code").

2. Vesting; Exercise. (a) The Option becomes exercisable in installments as provided on the *Notice of Grant of Stock Options*. To the extent that the Option has become exercisable with respect to the number of shares of Common Stock as provided on the *Notice of Grant of Stock Options* and subject to the terms and conditions of the Plan, including without limitation, Sections 7(c)(1) (if applicable) and 7(c)(2) of the Plan, the Option may thereafter be exercised by the Grantee, in whole or in part, at any time or from time to time prior to the expiration of the Option in accordance with the requirements set forth in Section 7(c)(3) of the Plan, including, without limitation, the filing of such written form of exercise notice as may be provided by the Company, and in accordance with applicable tax and other laws. In addition to the methods of payment described in Section 7(c)(3) of the Plan, the Grantee shall be eligible to pay for shares of Common Stock purchased upon the exercise of the Option by directing the Company to withhold shares of Common Stock that would otherwise be issued pursuant to the Option exercise having an aggregate Fair Market Value (as measured on the date of exercise) equal to the aggregate Option exercise price due upon such exercise. The Company shall have the right to require the Grantee in connection with the exercise of the Option to remit to the Company in cash an amount sufficient to satisfy any federal, state and local withholding tax requirements related thereto.

(b) The *Notice of Grant of Stock Options* indicates each date upon which the Grantee shall become entitled to exercise the Option with respect to the number of shares of Common Stock granted as indicated provided that [(except with respect to retirement on the terms set forth below)][1] the Grantee has not incurred a termination of employment or service with the Company and all Subsidiaries (the Company and all Subsidiaries shall be referred to herein, collectively, as the "Employer," and no termination of employment or service shall be deemed to take place unless the Grantee is no longer employed by or providing service to the Employer) prior to such date. There shall be no proportionate or partial vesting in the periods between the Full Vest Dates specified in the *Notice of Grant of Stock Options* and all vesting shall occur only on such Full Vest Dates. Except as otherwise provided below or in the Plan, no vesting shall occur after such date as the Grantee ceases to be employed by or provide services to the Employer and the entire unvested portion of the Option shall be forfeited at such time. [Notwithstanding the preceding sentence, upon the Grantee's retirement (as defined in the Company's employee handbook as in effect on the date hereof), the Option shall continue to vest in installments as provided in the *Notice of Grant*

[1] Only applicable to Option Agreements for George D. Yancopoulos, M.D., Ph.D.

of Stock Options as if the Grantee had continued to be employed by or provide services to the Employer.][2] For the avoidance of doubt and notwithstanding anything herein or in the *Notice of Grant of Stock Options* to the contrary, any outstanding and unvested portion of the Option shall become fully vested on the date of the Grantee's death. The provisions of this Section 2(b) are subject to (i) the provisions set forth in the *Notice of Grant of Stock Options* or any employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Grantee (or otherwise applicable to the Grantee) on the date of grant specified in the *Notice of Grant of Stock Options* and (ii) the Committee's determination in accordance with Section 7(e) of the Plan.

(c) Notwithstanding anything herein (except the following sentence) or in the *Notice of Grant of Stock Options* to the contrary, but subject to the provisions of any employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Grantee (or otherwise applicable to the Grantee) on the date of grant specified in the *Notice of Grant of Stock Options*, the Option shall be fully vested on the date of termination of the Grantee's employment with the Employer if the Grantee's employment with the Employer is terminated on or within two years after the occurrence of a Change in Control by the Employer (other than for Cause) or by the Grantee for Good Reason. Except as otherwise provided in any employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Grantee (or otherwise applicable to the Grantee) on the date of grant specified in the *Notice of Grant of Stock Options*, if the application of the provision in the foregoing sentence, similar provisions in other stock option or restricted stock grants, and other payments and benefits payable to the Grantee upon termination of employment with the Employer (collectively, the "Company Payments") would result in the Grantee being subject to the excise tax payable under Section 4999 of the Code (the "Excise Tax"), the amount of any Company Payments shall be automatically reduced to an amount one dollar less than an amount that would subject the Grantee to the Excise Tax; provided, however, that the reduction shall occur only if the reduced Company Payments received by the Grantee (after taking into account further reductions for applicable federal, state and local income, social security and other taxes) would be greater than the unreduced Company Payments to be received by the Grantee minus (i) the Excise Tax payable with respect to such Company Payments and (ii) all applicable federal, state and local income, social security and other taxes on such Company Payments. If the Company Payments are to be reduced in accordance with the foregoing, the Company Payments shall be reduced as mutually agreed between the Employer and the Grantee or, in the event the parties cannot agree, in the following order: (1) acceleration of vesting of any option where the exercise price exceeds the fair market value of the underlying shares at the time the acceleration would otherwise occur; (2) any lump-sum severance based on a multiple of base salary or bonus; (3) any other cash amounts payable to the Grantee; (4) any benefits valued as parachute payments; and (5) acceleration of vesting of any equity not covered by (1) above.

3. Option Term. (a) Except as otherwise provided in the next sentence or in the Plan, the Option shall expire on the tenth anniversary of the grant of the Option as shown on the *Notice of Grant of Stock Options*. In the event of termination of employment or service with the Employer, except as set forth in any employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Grantee (or otherwise applicable to the Grantee) on the date of grant specified in the *Notice of Grant of Stock Options*, or as may be otherwise determined by the Committee in accordance with Section 7(e) of the Plan, the vested portion of the Option shall expire on the earlier of (i) the tenth anniversary of this grant, or (ii)(A) subject to (E) below, three months after such termination if such termination is for any reason other than death, retirement (as defined in the Company's employee handbook as in effect on the date hereof), or long-term disability, (B) the tenth anniversary of this grant if such termination is due to the Grantee's retirement (as defined in the Company's employee handbook as in effect on the date hereof) [or the Grantee's death][3] [or the Grantee's death at a time when the Grantee is eligible for retirement (as defined in the Company's employee handbook as in effect on the date hereof)][4], (C) one year after the termination if such termination is due to the Grantee's [death at a time when the Grantee is not eligible for retirement (as defined in the Company's employee handbook as in effect on the date hereof) or due to the Grantee's][5] long-term disability, (D) the occurrence of the Cause event if such termination is for Cause or Cause existed at the time of such termination (whether then known or later discovered) or (E) one year after such termination if such termination is at any time within two years after the occurrence of a Change in Control and is by the Employer without Cause or by the Grantee for Good Reason. For the avoidance of doubt, any outstanding and unvested portion of the Option that has become fully vested as a result of termination of the Grantee's employment or service with the Employer on account of the

[2] Only applicable to Option Agreements for George D. Yancopoulos, M.D., Ph.D.
[3] Only applicable to Option Agreements for George D. Yancopoulos, M.D., Ph.D.
[4] Not applicable to Option Agreements for George D. Yancopoulos, M.D., Ph.D.
[5] Not applicable to Option Agreements for George D. Yancopoulos, M.D., Ph.D.

Grantee' death pur uant to Section 7(e)(2) of the Plan and Section 2(b) of thi Agreement shall expire [one year after uch termination][6] [on the tenth anniversary of this grant].[7]

(b) For purpo e of thi A reement, "Cau e" hall mean (i) in the ca e where there i no employment a reement, con ulting a reement, change in control agreement or plan, or similar agreement or plan in effect between the Company and the Grantee (or otherwise applicable to the Grantee) on the date of grant specified in the *Notice of Grant of Stock Options* (or where there is such an agreement or plan but it does not define "cause" (or words of like import)) (A) the willful and continued failure by the Grantee substantially to perform his or her duties and obligations to the Employer (other than any such failure resulting from his or her incapacity due to physical or mental illness), including without limitation, repeated refusal to follow the rea onable direction of the Employer, violation of the Employer' Code of Bu ine Conduct and Ethic , knowin violation of law in the cour e of performance of the duties of the Grantee's employment with the Employer, repeated absences from work without a reasonable excuse, or intoxication with alcohol or illegal drugs while on the Employer's premises during regular business hours; (B) fraud or material dishonesty against the Employer; or (C) a conviction or plea of guilty or nolo contendere to a felony or a crime involving material dishonesty; or (ii) in the case where there is an employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Grantee (or otherwi e applicable to the Grantee) on the date of rant pecified in the *Notice of Grant of Stock Options* that define "cau e" (or word of like import), a defined under such agreement or plan. For purposes of this Section 3(b), no act, or failure to act, on a Grantee's part shall be considered "willful" unless done, or omitted to be done, by the Grantee in bad faith and without reasonable belief that his or her action or omission was in the best interest of the Employer. Any determination of Cause made prior to a Change in Control shall be made by the Committee in its sole discretion.

(c) For purposes of this Agreement, "Good Reason" shall mean (i) in the case where there is no employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Grantee (or otherwise applicable to the Grantee) on the date of grant specified in the *Notice of Grant of Stock Options* (or where there is such an agreement or plan but it does not define "good rea on" (or word of like import)) a termination of employment by the Grantee within one hundred and twenty (120) day after the occurrence of one of the following events after the occurrence of a Change in Control unless such events are fully corrected in all material respects by the Employer within thirty (30) days following written notification by the Grantee to the Employer that Grantee intends to terminate his employment hereunder for one of the reasons set forth below: (A) (1) any material diminution in the Grantee's duties and responsibilities from those which existed immediately prior to a Change in Control (except in each case in connection with the termination of the Grantee's employment for Cause or as a result of the Grantee's death, or temporarily a a re ult of the Grantee' illne or other ab ence), or (2) the a i nment to the Grantee of dutie and re pon ibilitie materially incon i tent with the position held by the Grantee; (B) any material breach by the Employer of any material provision of any written agreement with the Grantee or failure to timely pay any compensation obligation to the Grantee; (C) a reduction in the Grantee's annual base salary or target bonus opportunity (if any) from that which existed immediately prior to a Change in Control; or (D) if the Grantee is based at the Employer's principal executive office, any relocation therefrom or, in any event, a relocation of the Grantee's primary office of more than fifty (50) miles from the location immediately prior to a Change in Control; or (ii) in the ca e where there i an employment a reement, con ulting a reement, change in control a reement or plan, or imilar a reement or plan in effect between the Employer and the Grantee (or otherwise applicable to the Grantee) on the date of grant specified in the *Notice of Grant of Stock Options* that defines "good reason" (or words of like import), as defined under such agreement or plan[; provided, however, that any such definition shall be deemed, solely for purposes of this Agreement, to include as one of the reasons that the employment of Leonard S. Schleifer, M.D., Ph.D. with the Company under the Amended and Restated Employment Agreement, dated as of November 14, 2008, by and between Dr. Schleifer and the Company, as in effect from time to time (the "Employment Agreement"), ha ended due to Dr Schleifer' Involuntary Termination (a defined in the Employment Agreement)][8].

4 Re triction on Tran fer of Option The Option ranted hereby shall not be transferable other than by will or by the law of de cent and distribution. During the lifetime of the Grantee, this Option shall be exercisable only by the Grantee. In addition, except as otherwise provided in this Agreement, the Option shall not be assigned, negotiated, pledged or hypothecated in any way (whether by operation of law or otherwise), and the Option shall not be subject to execution, attachment or similar process. Upon any other attempt to transfer, assign, negotiate, pledge or hypothecate the Option, or in the event of any levy upon the option by reason of any execution, attachment, or similar process contrary to the provisions hereof, the Option shall immediately become null and void Notwith tandin the fore oin provi ion of thi Section 4, ubject to the approval of the Committee in it ole and absolute discretion and to any conditions that the Committee may prescribe, the Grantee may, upon providing written notice to the Company, elect to transfer the Option to members of his or her immediate family, including, but not limited to, children, grandchildren and spouse or to trusts for the benefit of such immediate family

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[6] Not applicable to Option Agreements for George D. Yancopoulos, M.D., Ph.D.
[7] Only applicable to Option Agreements for George D. Yancopoulos, M.D., Ph.D.
[8] Only applicable to Option Agreements for George D. Yancopoulos, M.D., Ph.D.

members or to partnerships in which such family members are the only partners; provided, however, that no such transfer may be made in exchange for consideration.

5. Rights of a Shareholder. The Grantee shall have no rights as a shareholder with respect to any shares of Common Stock subject to this Option prior to the date of issuance to the Grantee of a certificate or certificates or book-entry registration or registrations for such shares. Except as provided in Section 3(c) of the Plan, no adjustment shall be made for dividends in cash or other property, distributions, or other rights with respect to such shares for which the record date is prior to the date upon which the Grantee shall become the holder of record therefor. The Company may, in its sole discretion, determine to deliver any documents related to participation in the Plan or deliverable to the Grantee in the Grantee's capacity as a shareholder of the Company by electronic means. The Grantee hereby consents to receive any and all such documents by electronic delivery to the extent the Company utilizes such delivery method from time to time.

6. Compliance with Law and Regulations. This Agreement, the award hereunder and any obligation of the Company hereunder shall be subject to all applicable federal, state and local laws, rules and regulations and to such approvals by any government or regulatory agency as may be required. The Company shall be under no obligation to effect the registration pursuant to federal securities laws of any interests in the Plan or any shares of Common Stock to be issued hereunder or to effect similar compliance under any state laws. The Company shall not be obligated to cause to be issued or delivered any certificates or register book entries evidencing shares of Common Stock pursuant to this Agreement unless and until the Company is advised by its counsel that the issuance and delivery of such certificates or the registration of such book entries is in compliance with all applicable laws, regulations of governmental authority and the requirements of any securities exchange on which shares of Common Stock are traded. The Committee may require, as a condition of the issuance and delivery of certificates or the registration of book entries evidencing shares of Common Stock pursuant to the terms hereof, that the recipient of such shares make such agreements and representations, and that such certificates and book entries bear or be subject to such legends, as the Committee, in its sole discretion, deems necessary or desirable. Except to the extent preempted by any applicable federal law, this Agreement shall be construed and administered in accordance with the laws of the State of New York without reference to its principles of conflicts of law.

7. Grantee Bound by Plan. The Grantee acknowledges receipt of a copy of the Plan and agrees to be bound by all the terms and provisions thereof, which are incorporated herein by reference. To the extent that this Agreement is silent with respect to, or in any way inconsistent with, the terms of the Plan, the provisions of the Plan shall govern and this Agreement shall be deemed to be modified accordingly.

8. Notices. Any notice or communication given hereunder shall be in writing and shall be deemed given when delivered in person, or by United States mail, at the following addresses: (i) if to the Employer, to: Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, Attention: Secretary, and (ii) if to the Grantee, to: the Grantee at Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, or, if the Grantee has terminated employment, to the last address for the Grantee indicated in the records of the Employer, or such other address as the relevant party shall specify at any time hereafter in accordance with this Section 8.

9. No Obligation to Continue Employment. This Agreement does not guarantee that the Employer will employ the Grantee for any specified time period, nor does it modify in any respect the Grantee's employment or compensation.

10. Recoupment. By entering into this Agreement and accepting the award hereunder, the Grantee agrees to be bound by the terms of the Company's Policy Regarding Recoupment or Reduction of Incentive Compensation for Compliance Violations, as in effect from time to time (or any successor policy thereto) (the "Recoupment Policy"), and further acknowledges and agrees that the Recoupment Policy shall apply to the Option and any shares of Common Stock issued pursuant thereto.

Regeneron Pharmaceuticals, Inc.
ID: [ ]
777 Old Saw Mill River Road
Tarrytown, New York 10591

Notice of Grant of Stock Options and Option Agreement for Time-Based Vesting Option Awards

[OPTIONEE NAME]
[OPTIONEE ADDRESS]

Option Number: **[ ]**
Plan: **[ ]**
ID: **[ ]**

Effective <date> (the "Grant Date") you have been granted a Non-Qualified Option to buy [ ] shares of Regeneron Pharmaceuticals, Inc. (the "Company") stock at $[ ] per share.

The total option price of the shares granted is $[ ].

Shares in each period will become fully vested on the date shown.

Shares	Vest Type	Full Vest	Expiration Date
**	On Vest Date	[__/__/__]**	[10 years from Grant Date]
**	On Vest Date	[__/__/__]**	[10 years from Grant Date]
**	On Vest Date	[__/__/__]**	[10 years from Grant Date]
**	On Vest Date	[__/__/__]**	[10 years from Grant Date]

The Non-Qualified Stock Option expires on [ ]*** (the "Expiration Date").

You and the Company agree that these options are granted under and governed by the terms and conditions of the Second Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long Term Incentive Plan, as amended from time to time, and the enclosed Option Agreement, both of which are attached and made a part of this document.

** Options will vest in approximately equal annual 25% installments. Full Vest Dates will occur on the first, second, third and fourth anniversaries of the Grant Date.

*** Date to be 10 years from the Grant Date.

REGENERON PHARMACEUTICALS, INC.

Non-Qualified Stock Option

OPTION AGREEMENT
PURSUANT TO
THE SECOND AMENDED AND RESTATED REGENERON PHARMACEUTICALS, INC.
2014 LONG-TERM INCENTIVE PLAN

THIS AGREEMENT (this "Agreement"), made as of the date of the *Notice of Grant of Stock Options*, by and between Regeneron Pharmaceuticals, Inc., a New York corporation (the "Company"), and the employee named on the *Notice of Grant of Stock Options* (the "Grantee"). Any capitalized term used but not defined in this Agreement shall have the meaning given to such term in the Plan (as defined below).

WHEREAS, the Grantee is an employee of the Company (or a Subsidiary of the Company) and the Company desires to afford the Grantee the opportunity to acquire or enlarge the Grantee's stock ownership in the Company so that the Grantee may have a direct proprietary interest in the Company's success; and

WHEREAS, the Committee (or the person or persons to whom the Committee has delegated the relevant authority pursuant to Section 4 of the Plan (as defined below) (the Committee or such person or persons being referred to in this Agreement as the "Committee")) administering the Second Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (as amended from time to time, the "Plan") has granted (as of the effective date of grant specified in the *Notice of Grant of Stock Options*) to the Grantee a Stock Option to purchase the number of shares of the Company's common stock, $0.001 par value per share (the "Common Stock"), as set forth in the *Notice of Grant of Stock Options*.

NOW, THEREFORE, in consideration of the covenants and agreements herein contained, the parties agree as follows:

1. Grant of Award. Pursuant to Section 7 of the Plan, the Company grants to the Grantee, subject to the terms and conditions of the Plan and subject further to the terms and conditions set forth herein, the option (the "Option") to purchase from the Company all or any part of an aggregate of shares of Common Stock at the purchase price per share as shown on the *Notice of Grant of Stock Options*. No part of the Option granted hereby is intended to qualify as an Incentive Stock Option under Section 422 of the Internal Revenue Code of 1986, as amended (the "Code").

2. Vesting; Exercise. (a) The Option becomes exercisable in installments as provided on the *Notice of Grant of Stock Options*. To the extent that the Option has become exercisable with respect to the number of shares of Common Stock as provided on the *Notice of Grant of Stock Options* and subject to the terms and conditions of the Plan, including without limitation, Sections 7(c)(1) (if applicable) and 7(c)(2) of the Plan, the Option may thereafter be exercised by the Grantee, in whole or in part, at any time or from time to time prior to the expiration of the Option in accordance with the requirements set forth in Section 7(c)(3) of the Plan, including, without limitation, the filing of such written form of exercise notice as may be provided by the Company, and in accordance with applicable tax and other laws. In addition to the methods of payment described in Section 7(c)(3) of the Plan, the Grantee shall be eligible to pay for shares of Common Stock purchased upon the exercise of the Option by directing the Company to withhold shares of Common Stock that would otherwise be issued pursuant to the Option exercise having an aggregate Fair Market Value (as measured on the date of exercise) equal to the aggregate Option exercise price due upon such exercise. The Company shall have the right to require the Grantee in connection with the exercise of the Option to remit to the Company in cash an amount sufficient to satisfy any federal, state and local withholding tax requirements related thereto.

(b) The *Notice of Grant of Stock Options* indicates each date upon which the Grantee shall become entitled to exercise the Option with respect to the number of shares of Common Stock granted as indicated provided that (except with respect to retirement on the terms set forth below) the Grantee has not incurred a termination of employment or service with the Company and all Subsidiaries (the Company and all Subsidiaries shall be referred to herein, collectively, as the "Employer," and no termination of employment or service shall be deemed to take place unless the Grantee is no longer employed by or providing service to the Employer) prior to such date. There shall be no proportionate or partial vesting in the periods between the Full Vest Dates specified in the *Notice of Grant of Stock Options* and all vesting shall occur only on such Full Vest Dates. Except as otherwise provided below or in the Plan, no vesting shall occur after such date as the Grantee ceases to be employed by or provide services to the Employer and the entire unvested portion of the Option shall be forfeited at such time. Notwithstanding the preceding sentence, upon the Grantee's retirement (as defined in the Company's employee handbook as in effect on the date hereof), the Option shall continue to vest in installments as provided in the *Notice of Grant of Stock Options* as if the Grantee had continued to be employed by or provide services to the Employer. For the avoidance of doubt and notwithstanding anything herein or in the *Notice of Grant of Stock Options* to the contrary, any outstanding and

unvested portion of the Option shall become fully vested on the date of the Grantee's death. The provisions of this Section 2(b) are subject to (i) the provisions set forth in the *Notice of Grant of Stock Options* or any employment agreement, consulting agreement or similar agreement in effect between the Employer and the Grantee (or otherwi e applicable to the Grantee) on the date of rant pecified in the *Notice of Grant of Stock Options* and (ii) the Committee's determination in accordance with Section 7(e) of the Plan.

(c) Notwith tanding anythin herein (except the following entence) or in the *Notice of Grant of Stock Options* to the contrary, the Option shall be fully vested on the date of a Change in Control. Except as otherwise provided in any employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Grantee (or otherwise applicable to the Grantee) on the date of grant specified in the *Notice of Grant of Stock Options*, if the application of the provision in the foregoing sentence, similar provisions in other stock option or restricted stock grants, and other payments and benefits payable to the Grantee upon termination of employment with the Employer (collectively, the "Company Payment ") would re ult in the Grantee bein ubject to the exci e tax payable under Section 4999 of the Code (the "Exci e Tax"), the amount of any Company Payments shall be automatically reduced to an amount one dollar less than an amount that would subject the Grantee to the Excise Tax; provided, however, that the reduction shall occur only if the reduced Company Payments received by the Grantee (after taking into account further reductions for applicable federal, state and local income, social security and other taxes) would be greater than the unreduced Company Payments to be received by the Grantee minus (i) the Excise Tax payable with respect to such Company Payments and (ii) all applicable federal, state and local income, ocial ecurity and other taxe on uch Company Payment If the Company Payment are to be reduced in accordance with the fore oing, the Company Payments shall be reduced as mutually agreed between the Employer and the Grantee or, in the event the parties cannot agree, in the following order: (1) acceleration of vesting of any option where the exercise price exceeds the fair market value of the underlying shares at the time the acceleration would otherwise occur; (2) any lump-sum severance based on a multiple of base salary or bonus; (3) any other cash amounts payable to the Grantee; (4) any benefits valued as parachute payments; and (5) acceleration of vesting of any equity not covered by (1) above.

3. Option Term. (a) Except as otherwise provided in the next sentence or in the Plan, the Option shall expire on the tenth anniversary of the grant of the Option as shown on the *Notice of Grant of Stock Options*. In the event of termination of employment or service with the Employer, except as may be determined by the Committee in accordance with Section 7(e) of the Plan, the vested portion of the Option shall expire on the earlier of (i) the tenth anniversary of this grant, or (ii)(A) subject to (E) below, three months after such termination if such termination is for any reason other than death, retirement (as defined in the Company's employee handbook as in effect on the date hereof), or long-term disability; (B) the tenth anniversary of this grant if such termination is due to the Grantee's retirement (as defined in the Company's employee handbook as in effect on the date hereof) or the Grantee's death; (C) one year after the termination if such termination is due to the Grantee's long-term disability; (D) the occurrence of the Cause event if such termination is for Cause or Cause existed at the time of such termination (whether then known or later discovered); or (E) one year after such termination if such termination is at any time within two years after the occurrence of a Change in Control and is not due to death, retirement, or long-term disability. For the avoidance of doubt, any outstanding and unvested portion of the Option that has become fully vested as a result of termination of the Grantee's employment or service with the Employer on account of the Grantee's death pursuant to Section 7(e)(2) of the Plan and Section 2(b) of this Agreement shall expire on the tenth anniversary of this grant.

(b) For purposes of this Agreement, "Cause" shall mean (i) in the case where there is no employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Company and the Grantee (or otherwise applicable to the Grantee) on the date of grant specified in the *Notice of Grant of Stock Options* (or where there is such an agreement or plan but it does not define "cause" (or words of like import)) (A) the willful and continued failure by the Grantee substantially to perform his or her duties and obligations to the Employer (other than any such failure resulting from his or her incapacity due to physical or mental illness), including without limitation, repeated refusal to follow the reasonable directions of the Employer, violation of the Employer's Code of Business Conduct and Ethics, knowing violation of law in the course of performance of the duties of the Grantee's employment with the Employer, repeated absences from work without a reasonable excuse, or intoxication with alcohol or illegal drugs while on the Employer's premises during regular business hours; (B) fraud or material dishonesty against the Employer; or (C) a conviction or plea of guilty or nolo contendere to a felony or a crime involving material dishonesty; or (ii) in the case where there is an employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Grantee (or otherwise applicable to the Grantee) on the date of grant specified in the *Notice of Grant of Stock Options* that defines "cause" (or words of like import), as defined under such agreement or plan. For purposes of this Section 3(b), no act, or failure to act, on a Grantee's part shall be considered "willful" unless done, or omitted to be done, by the Grantee in bad faith and without reasonable belief that his or her action or omission was in the best interest of the Employer. Any determination of Cause made prior to a Change in Control shall be made by the Committee in its sole discretion.

4. Restrictions on Transfer of Option. The Option granted hereby shall not be transferable other than by will or by the laws of descent and distribution. During the lifetime of the Grantee, this Option shall be exercisable only by the Grantee. In addition, except as otherwise provided in this A reement, the Option shall not be a igned, ne otiated, pled ed or hypothecated in any way (whether by operation of law or otherwi e), and the Option shall not be subject to execution, attachment or similar process. Upon any other attempt to transfer, assign, negotiate, pledge or hypothecate the Option, or in the event of any levy upon the option by reason of any execution, attachment, or similar process contrary to the provisions hereof, the Option shall immediately become null and void. Notwithstanding the foregoing provisions of this Section 4, subject to the approval of the Committee in its sole and absolute discretion and to any conditions that the Committee may prescribe, the Grantee may, upon providing written notice to the Company, elect to tran fer the Option to member of hi or her immediate family, including, but not limited to, children, randchildren and pou e or to tru t for the benefit of such immediate family members or to partnerships in which such family members are the only partners; provided, however, that no such transfer may be made in exchange for consideration.

5. Rights of a Shareholder. The Grantee shall have no rights as a shareholder with respect to any shares of Common Stock subject to this Option prior to the date of issuance to the Grantee of a certificate or certificates or book-entry registration or registrations for such shares. Except as provided in Section 3(c) of the Plan, no adjustment shall be made for dividends in cash or other property, distributions, or other rights with respect to such shares for which the record date is prior to the date upon which the Grantee shall become the holder of record therefor. The Company may, in its sole di cretion, determine to deliver any document related to participation in the Plan or deliverable to the Grantee in the Grantee' capacity a a shareholder of the Company by electronic means. The Grantee hereby consents to receive any and all such documents by electronic delivery to the extent the Company utilizes such delivery method from time to time.

6. Compliance with Law and Regulations. This Agreement, the award hereunder and any obligation of the Company hereunder shall be subject to all applicable federal, state and local laws, rules and regulations and to such approvals by any government or regulatory agency as may be required. The Company shall be under no obligation to effect the registration pursuant to federal securities laws of any interests in the Plan or any shares of Common Stock to be issued hereunder or to effect similar compliance under any state laws. The Company shall not be obligated to cause to be issued or delivered any certificate or re i ter book entrie evidencin hare of Common Stock pur uant to thi A reement unle and until the Company i advi ed by its counsel that the issuance and delivery of such certificates or the registration of such book entries is in compliance with all applicable laws, regulations of governmental authority and the requirements of any securities exchange on which shares of Common Stock are traded. The Committee may require, as a condition of the issuance and delivery of certificates or the registration of book entries evidencing shares of Common Stock pursuant to the terms hereof, that the recipient of such shares make such agreements and representations, and that such certificates and book entries bear or be subject to uch le end , a the Committee, in it ole di cretion, deem nece ary or de irable Except to the extent preempted by any applicable federal law, thi Agreement shall be construed and administered in accordance with the laws of the State of New York without reference to its principles of conflicts of law.

7 Grantee Bound by Plan The Grantee acknowled e receipt of a copy of the Plan and a ree to be bound by all the term and provi ion thereof, which are incorporated herein by reference. To the extent that this Agreement is silent with respect to, or in any way inconsistent with, the terms of the Plan, the provisions of the Plan shall govern and this Agreement shall be deemed to be modified accordingly.

8. Notices. Any notice or communication given hereunder shall be in writing and shall be deemed given when delivered in person, or by United States mail, at the following addresses: (i) if to the Employer, to: Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, Attention: Secretary, and (ii) if to the Grantee, to: the Grantee at Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, or, if the Grantee has terminated employment, to the last address for the Grantee indicated in the records of the Employer, or such other address as the relevant party hall pecify at any time hereafter in accordance with thi Section 8

9. No Obligation to Continue Employment. This Agreement does not guarantee that the Employer will employ the Grantee for any specified time period, nor doe it modify in any re pect the Grantee' employment or compen ation

10. Recoupment. By entering into this Agreement and accepting the award hereunder, the Grantee agrees to be bound by the terms of the Company' Policy Re arding Recoupment or Reduction of Incentive Compen ation for Compliance Violation , a in effect from time to time (or any successor policy thereto) (the "Recoupment Policy"), and further acknowledges and agrees that the Recoupment Policy shall apply to the Option and any shares of Common Stock issued pursuant thereto.

Notice of Grant of Award and Restricted Stock Agreement

Regeneron Pharmaceuticals, Inc.
ID: [ ]
777 Old Saw Mill River Road
Tarrytown, New York 10591

[NAME]
[ADDRESS]

RSA Number: **[ ]**
Plan: **[ ]**
ID: **[ ]**

Effective <date> (the "Grant Date") you have been granted an award of [ ] shares of Regeneron Pharmaceuticals, Inc. (the "Company") common stock. These shares are restricted until the vest date(s) shown below.

The current total value of the award is $[ ].

The award will vest in full on the date(s) shown.

Shares	Full Vest Date
[ ]*	[ ]*

You and the Company agree that this award is granted under and governed by the terms and conditions of the Second Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long Term Incentive Plan, as amended from time to time, and the enclosed Restricted Stock Agreement, both of which are attached and made a part of this document.

* Awards designated as annual awards will vest 50% on the second anniversary of the Grant Date and 50% on the fourth anniversary of the Grant Date. Awards to Senior Vice Presidents and Executive Vice Presidents designated as special awards will vest in their entirety on the fifth anniversary of the Grant Date. Awards to Vice Presidents designated as special awards will vest in their entirety on the fourth anniversary of the Grant Date.

REGENERON PHARMACEUTICALS, INC.

RESTRICTED STOCK AGREEMENT
PURSUANT TO
THE SECOND AMENDED AND RESTATED REGENERON PHARMACEUTICALS, INC.
2014 LONG-TERM INCENTIVE PLAN

THIS AGREEMENT (this "Agreement"), made as of the date on the *Notice of Grant of Restricted Stock*, by and between Regeneron Pharmaceuticals, Inc., a New York corporation (the "Company"), and the employee named on the *Notice of Grant of Restricted Stock* (the "Recipient"). Any capitalized term used but not defined in this Agreement shall have the meaning given to such term in the Plan (as defined below).

WHEREAS, the Recipient is an employee of the Company (or a Subsidiary of the Company) and the Company desires to afford the Recipient the opportunity to acquire or enlarge the Recipient's stock ownership in the Company so that the Recipient may have a direct proprietary interest in the Company's success; and

WHEREAS, the Committee administering the Second Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (as amended from time to time, the "Plan") has granted (as of the effective date of grant specified in the *Notice of Grant of Restricted Stock*) to the Recipient the shares of Restricted Stock as set forth in the *Notice of Grant of Restricted Stock*.

NOW, THEREFORE, in consideration of the covenants and agreements herein contained, the parties agree as follows:

1. **Grant of Award**. Pursuant to Section 8 of the Plan, the Company grants to the Recipient, subject to the terms and conditions of the Plan and subject further to the terms and conditions set forth herein, the number of shares of Restricted Stock as shown on the *Notice of Grant of Restricted Stock*. The Recipient's grant and record of Restricted Stock share ownership shall be kept on the books of the Company until the restrictions on transfer have lapsed. At the Recipient's request, vested shares may be evidenced by stock certificates or book-entry registration.

2. **Vesting**. (a) The shares of Restricted Stock granted to the Recipient shall vest in installments as provided in the *Notice of Grant of Restricted Stock*. The vesting schedule in the *Notice of Grant of Restricted Stock* indicates each date upon which the restrictions on transfer on the specified number of shares of Restricted Stock shall lapse, entitling the Recipient to freely transfer such shares, provided that the Recipient has not [(except with respect to retirement on the terms set forth below)][1] incurred a termination of employment with the Company and all Subsidiaries (the Company and its Subsidiaries shall be referred to herein, collectively, as the "Employer"). There shall be no proportionate or partial vesting in the periods between the Full Vest Dates specified in the *Notice of Grant of Restricted Stock* and all vesting shall occur only on such Full Vest Dates. No vesting shall occur after the termination of the Recipient's employment with the Employer for any reason [(except with respect to retirement on the terms set forth below)][2]. The provisions of this Section 2(a) are subject to (i) the provisions set forth in the *Notice of Grant of Restricted Stock* or any employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Recipient (or otherwise applicable to the Recipient) on the date of grant specified in the *Notice of Grant of Restricted Stock* and (ii) the Committee's determination in accordance with Section 8(h) of the Plan.

(b) Notwithstanding anything herein (except the following sentence) or in the *Notice of Grant of Restricted Stock* to the contrary, but subject to the provisions of any employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Recipient (or otherwise applicable to the Recipient) on the date of grant specified in the *Notice of Grant of Restricted Stock*, the Restricted Stock granted to Recipient shall be fully vested on the date the Recipient's

[1] Only applicable to Restricted Stock Agreements for George D. Yancopoulos, M.D., Ph.D.
[2] Only applicable to Restricted Stock Agreements for George D. Yancopoulos, M.D., Ph.D.

employment with the Employer is terminated if the Recipient's employment with the Employer is terminated on or within two years after the occurrence of a Change in Control by the Employer (other than for Cause) or by the Recipient for Good Reason. Except as otherwise provided in any employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Recipient (or otherwise applicable to the Recipient) on the date of grant specified in the *Notice of Grant of Restricted Stock*, if the application of the provision in the foregoing sentence, similar provisions in other stock option or restricted stock grants, and other payments and benefits payable to the Recipient upon termination of employment with the Employer (collectively, the "Company Payments") would result in the Recipient being subject to excise tax (the "Excise Tax") payable under Section 4999 of the Internal Revenue Code of 1986, as amended (the "Code"), the amount of any Company Payments shall be automatically reduced to an amount one dollar less than an amount that would subject the Recipient to the Excise Tax; provided, however, that the reduction shall occur only if the reduced Company Payments received by the Recipient (after taking into account further reductions for applicable federal, state and local income, social security and other taxes) would be greater than the unreduced Company Payments to be received by the Recipient minus (i) the Excise Tax payable with respect to such Company Payments and (ii) all applicable federal, state and local income, social security and other taxes on such Company Payments. If the Company Payments are to be reduced in accordance with the foregoing, the Company Payments shall be reduced as mutually agreed between the Employer and the Recipient or, in the event the parties cannot agree, in the following order: (1) acceleration of vesting of any option where the exercise price exceeds the fair market value of the underlying shares at the time the acceleration would otherwise occur; (2) any lump-sum severance based on a multiple of base salary or bonus; (3) any other cash amounts payable to the Recipient; (4) any benefits valued as parachute payments; and (5) acceleration of vesting of any equity not covered by (1) above.

(c) For purposes of this Agreement, "Cause" shall mean (i) in the case where there is no employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Recipient (or otherwise applicable to the Recipient) on the date of grant specified in the *Notice of Grant of Restricted Stock* (or where there is such an agreement or plan but it does not define "cause" (or words of like import)) (A) the willful and continued failure by the Recipient substantially to perform his or her duties and obligations to the Employer (other than any such failure resulting from his or her incapacity due to physical or mental illness), including without limitation, repeated refusal to follow the reasonable directions of the Employer, violation of the Employer's Code of Business Conduct and Ethics, knowing violation of law in the course of performance of the duties of the Recipient's employment with the Employer, repeated absences from work without a reasonable excuse, or intoxication with alcohol or illegal drugs while on the Employer's premises during regular business hours; (B) fraud or material dishonesty against the Employer; or (C) a conviction or plea of guilty or nolo contendere to a felony or a crime involving material dishonesty; or (ii) in the case where there is an employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Recipient (or otherwise applicable to the Recipient) on the date of grant specified on the *Notice of Grant of Restricted Stock* that defines "cause" (or words of like import), as defined under such agreement or plan. For purposes of this Section 2(c), no act, or failure to act, on the Recipient's part shall be considered "willful" unless done, or omitted to be done, by the Recipient in bad faith and without reasonable belief that his or her action or omission was in the best interest of the Employer. Any determination of Cause made prior to a Change in Control shall be made by the Committee in its sole discretion.

(d) For purposes of this Agreement, "Good Reason" shall mean (i) in the case where there is no employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Recipient (or otherwise applicable to the Recipient) on the date of grant specified in the *Notice of Grant of Restricted Stock* (or where there is such an agreement or plan but it does not define "good reason" (or words of like import)) a termination of employment by the Recipient within one hundred twenty (120) days after the occurrence of one of the following events after the occurrence of a Change in Control unless such events are fully corrected in all material respects by the Employer within thirty (30) days following written notification by the Recipient to the Employer that Recipient intends to terminate his employment hereunder for one of the reasons set forth below: (A) (1) any material diminution in the Recipient's duties and responsibilities from those which existed immediately prior to a Change in Control (except in each case in connection with the termination of the Recipient's employment for Cause or as a result of the Recipient's death, or temporarily as a result of the Recipient's illness or other absence), or (2) the assignment to the Recipient of duties and responsibilities materially inconsistent with the position held by the Recipient; (B) any material breach by the Employer of any

material provision of any written agreement with the Recipient or failure to timely pay any compensation obligation to the Recipient; (C) a reduction in the Recipient's annual base salary or target bonus opportunity (if any) from that which existed immediately prior to a Change in Control; or (D) if the Recipient is based at the Employer's principal executive office, any relocation therefrom or, in any event, a relocation of the Recipient's primary office of more than fifty (50) miles from the location immediately prior to a Change in Control; or (ii) in the case where there is an employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Recipient (or otherwise applicable to the Recipient) on the date on the *Notice of Grant of Restricted Stock* that defines "good reason" (or words of like import), as defined under such agreement or plan[; provided, however, that any such definition shall be deemed, solely for purposes of this Agreement, to include as one of the reasons that the employment of Leonard S. Schleifer, M.D. Ph.D. with the Company under the Amended and Restated Employment Agreement, dated as of November 14, 2008, by and between Dr. Schleifer and the Company, as in effect from time to time (the "Employment Agreement"), has ended due to Dr. Schleifer's Involuntary Termination (as defined in the Employment Agreement)][3].

3. **Termination of Service**. Subject to the terms of the Plan and Section 2(b) hereof, if the Recipient's employment with the Company is terminated for any reason (other than as set forth in Section 2(b) hereof and as a result of Recipient's [retirement on the terms set forth below or][4] death), the Recipient shall forfeit any or all of the shares of Restricted Stock that have not vested in accordance with Section 2 hereof (the "Unvested Shares"). [Notwithstanding the preceding sentence, upon the Recipient's retirement (as defined in the Company's employee handbook as in effect on the date hereof), shares of Restricted Stock granted to the Recipient shall continue to vest in installments as provided in the *Notice of Grant of Restricted Stock* as if the Recipient had continued to be employed by or provide services to the Employer.][5] Shares of Restricted Stock granted to the Recipient in the Notice of Grant of Restricted Stock shall become fully vested as of the date of death of the Recipient, provided that the Recipient is employed by the Employer on the date of his/her death.

4. **Restrictions on Transfer**. Unvested Shares may not be transferred or otherwise disposed of by the Recipient including by way of sale, assignment, transfer, pledge, hypothecation or otherwise, except as permitted by the Committee in its sole discretion.

5. **Securities Laws Requirements**. The Company shall not be obligated to transfer any Unvested Shares or other shares of Company Stock to the Recipient, if such transfer, in the opinion of counsel for the Company, would violate the Securities Act (or any other federal or state statutes having similar requirements as may be in effect at that time).

6. **Invalid Transfers**. No purported sale, assignment, mortgage, hypothecation, transfer, pledge, encumbrance, gift, transfer in trust (voting or other) or other disposition of, or creation of a security interest in or lien on, any of the shares of Restricted Stock by any holder thereof in violation of the provisions of this Agreement or the Certificate of Incorporation or the By-Laws of the Company, shall be valid, and the Company will not transfer any of said shares of Restricted Stock on its books nor will any of said shares of Restricted Stock be entitled to vote, nor will any dividends be paid thereon, unless and until there has been full compliance with said provisions to the satisfaction of the Company. The foregoing restrictions are in addition to and not in lieu of any other remedies, legal or equitable, available to enforce said provisions.

7. **Taxes**. The Recipient shall promptly notify the Company of any election made pursuant to Section 83(b) of the Code. The Recipient shall pay to the Company, at the time the Recipient recognizes taxable income in respect to the shares of Restricted Stock as a result of having made an election under Section 83(b) of the Code in connection with such grant, an amount equal to the federal, state and/or local taxes the Company determines it is required to withhold under applicable tax laws with respect to the shares of Restricted Stock. The Recipient may satisfy the foregoing requirement by making a payment to the Company in cash or, with the consent of the Company, by authorizing the Company to withhold cash otherwise due to the Recipient. In all other cases (except as may be otherwise determined by the Board of Directors or the Committee from time to time (including following the date hereof)), any such withholding obligation shall be satisfied by surrendering to the Company a portion of the

[3] Only applicable to Restricted Stock Agreements for George D. Yancopoulos, M.D., Ph.D.
[4] Only applicable to Restricted Stock Agreements for George D. Yancopoulos, M.D., Ph.D.
[5] Only applicable to Restricted Stock Agreements for George D. Yancopoulos, M.D., Ph.D.

shares of Restricted Stock the vesting of which gives rise to the withholding obligation (but only to the extent of the minimum withholding required by law). Shares so surrendered by the Recipient shall be credited against any such withholding obligation at the Fair Market Value of such shares on the date of such vesting (and the amount equal to the Fair Market Value of such shares shall be remitted by the Company to the appropriate tax authorities). The Recipient understands that he or she (and not the Company) shall be responsible for any tax liability that may arise as a result of the transactions contemplated by this Agreement.

THE RECIPIENT ACKNOWLEDGES THAT IT IS THE RECIPIENT'S SOLE RESPONSIBILITY, AND NOT THE COMPANY'S, TO FILE TIMELY THE ELECTION UNDER SECTION 83(b) OF THE CODE, IN THE EVENT THAT THE RECIPIENT DESIRES TO MAKE THE ELECTION.

8. **Rights as a Shareholder**. Pursuant to Section 8(e) of the Plan, the Company shall hold in escrow all dividends, if any, that are paid with respect to the Unvested Shares until all restrictions on such shares have lapsed. Pursuant to Section 8(f) of the Plan, the Recipient agrees (i) that the right to vote any Unvested Shares will be held by the Company and (ii) to execute an irrevocable proxy in favor of the Company in such form supplied by the Company. The Company may, in its sole discretion, determine to deliver any documents related to participation in the Plan or deliverable to the Recipient in the Recipient's capacity as a shareholder of the Company by electronic means. The Recipient hereby consents to receive any and all such documents by electronic delivery to the extent the Company utilizes such delivery method from time to time.

9. **Compliance with Law and Regulations**. This Agreement, the award hereunder and any obligation of the Company hereunder shall be subject to all applicable federal, state and local laws, rules and regulations and to such approvals by any government or regulatory agency as may be required. The Company may require, as a condition of the issuance and delivery of certificates or the registration of book entries evidencing Restricted Stock pursuant to the terms hereof, that the certificates or book entries bear or be subject to such legends as set forth in the Plan, in addition to any other legends required under federal and state securities laws or as otherwise determined by the Committee. Except to the extent preempted by any federal law, this Agreement shall be construed and administered in accordance with the laws of the State of New York without reference to its principles of conflicts of law.

10. **Recipient Bound by Plan**. The Recipient acknowledges receipt of a copy of this Agreement and the Plan and agrees to be bound by all the terms and provisions thereof, which are incorporated herein by reference. To the extent that this Agreement is silent with respect to, or in any way inconsistent with, the terms of the Plan, the provisions of the Plan shall govern and this Agreement shall be deemed to be modified accordingly.

11. **Notices**. Any notice or communication given hereunder shall be in writing and shall be deemed given when delivered in person, or by United States mail, at the following addresses: (i) if to the Company, to: Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, Attention: Secretary, and (ii) if to the Recipient, to: the Recipient at Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, or, if the Recipient has terminated service with the Company, to the last address for the Recipient indicated in the records of the Company, or such other address as the relevant party shall specify at any time hereafter in accordance with this Section 11.

12. **No Obligation to Continue Employment**. This Agreement does not guarantee that the Employer will employ the Recipient for any specified time period, nor does it modify in any respect the Recipient's employment or compensation.

13. **Recoupment**. By entering into this Agreement and accepting the award hereunder, the Recipient agrees to be bound by the terms of the Company's Policy Regarding Recoupment or Reduction of Incentive Compensation for Compliance Violations, as in effect from time to time (or any successor policy thereto) (the "Recoupment Policy"), and further acknowledges and agrees that the Recoupment Policy shall apply to the shares of Restricted Stock granted hereunder (including after all restrictions on such shares have lapsed).

Notice of Grant of Restricted Stock Units and Restricted Stock Unit Agreement

Regeneron Pharmaceuticals, Inc.
ID: [ ]
777 Old Saw Mill River Road
Tarrytown, New York 10591

[NAME]
[ADDRESS]

RSU Number: [ ]
Plan: [ ]
ID: [ ]

Effective <date> (the "Grant Date") you have been granted restricted stock units with respect to [ ] shares of Regeneron Pharmaceuticals, Inc. (the "Company") common stock.

The current total value of the award is $[ ].

The award will vest in full on the date(s) shown.

Shares	Full Vest Date
[ ]*	[ ]*

You and the Company agree that this award is granted under and governed by the terms and conditions of the Second Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long Term Incentive Plan, as amended from time to time, and the enclosed Restricted Stock Unit Agreement, both of which are attached and made a part of this document.

* Awards will vest 50% on the second anniversary of the Grant Date and 50% on the fourth anniversary of the Grant Date.

REGENERON PHARMACEUTICALS, INC.

RESTRICTED STOCK UNIT AGREEMENT
PURSUANT TO
THE SECOND AMENDED AND RESTATED REGENERON PHARMACEUTICALS, INC.
2014 LONG-TERM INCENTIVE PLAN

THIS AGREEMENT (this "Agreement"), made as of the date on the *Notice of Grant of Restricted Stock Units*, by and between Regeneron Pharmaceuticals, Inc., a New York corporation (the "Company"), and the employee named on the *Notice of Grant of Restricted Stock Units* (the "Recipient"). Any capitalized term used but not defined in this Agreement shall have the meaning given to such term in the Plan (as defined below).

WHEREAS, the Recipient is an employee of the Company (or a Subsidiary of the Company) and the Company desires to afford the Recipient the opportunity to acquire or enlarge the Recipient's stock ownership in the Company so that the Recipient may have a direct proprietary interest in the Company's success; and

WHEREAS, the Committee (or the person or persons to whom the Committee has delegated the relevant authority pursuant to Section 4 of the Plan (as defined below) (the Committee or such person or persons being referred to in this Agreement as the "Committee")) administering the Second Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (as amended from time to time, the "Plan") has granted (as of the effective date of grant specified in the *Notice of Grant of Restricted Stock Units*) to the Recipient a Restricted Stock Unit (as defined below) with respect to the number of shares of Company Stock as set forth in the *Notice of Grant of Restricted Stock Units*.

NOW, THEREFORE, in consideration of the covenants and agreements herein contained, the parties agree as follows:

1. **Grant of Award**. Pursuant to Section 9 of the Plan, the Company grants to the Recipient, subject to the terms and conditions of the Plan and subject further to the terms and conditions set forth herein, a restricted stock unit (referred to in the Plan as "Phantom Stock") (each such unit, a "Restricted Stock Unit") with respect to the number of shares of Company Stock as shown on the Notice of Grant of Restricted Stock Units. The Participant's record of Company Stock ownership shall be recorded in the books of the Company only when the Restricted Stock Units vest and the shares of Company Stock are issued. At the Recipient's request, vested shares may be evidenced by stock certificates or book-entry registration.

2. **Vesting; Delivery**. (a) The Restricted Stock Units granted to the Recipient shall vest in installments as provided in the Notice of Grant of Restricted Stock Units. The vesting schedule in the Notice of Grant of Restricted Stock Units indicates each date upon which the Restricted Stock Units shall vest, entitling the Recipient to receive the underlying shares of Company Stock, provided that the Recipient has not (except with respect to retirement on the terms set forth below) incurred a termination of employment with the Company and all Subsidiaries (the Company and its Subsidiaries shall be referred to herein, collectively, as the "Employer"). For the avoidance of doubt, and notwithstanding any provision in this Agreement or the Plan to the contrary, no termination of employment shall be deemed to take place unless the Recipient has ceased both to be employed by and to provide service to the Employer. There shall be no proportionate or partial vesting in the periods between the Full Vest Dates specified in the Notice of Grant of Restricted Stock Units and all vesting shall occur only on such Full Vest Dates. No vesting shall occur after the termination of the Recipient's employment with the Employer for any reason (except with respect to retirement on the terms set forth below). The provisions of this Section 2(a) are subject to (i) the provisions set forth in the Notice of Grant of Restricted Stock Units or any employment agreement, consulting agreement or similar agreement in effect between the Employer and the Recipient (or otherwise applicable to the Recipient) on the date of grant specified in the Notice of Grant of Restricted Stock Units and (ii) the Committee's determination in accordance with Section 9(d) of the Plan.

(b) Notwithstanding anything herein (except the following sentence) or in the Notice of Grant of Restricted Stock Units to the contrary, the Restricted Stock Units granted to Recipient shall be fully vested

on the date of a Change in Control. Except as otherwise provided in any employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Recipient (or otherwise applicable to the Recipient) on the date of grant specified in the Notice of Grant of Restricted Stock Units, if the application of the provision in the foregoing sentence, similar provisions in other stock option or equity compensation grants, and other payments and benefits payable to the Recipient upon termination of employment with the Employer (collectively, the "Company Payments") would result in the Recipient being subject to excise tax (the "Excise Tax") payable under Section 4999 of the Internal Revenue Code of 1986, as amended (the "Code"), the amount of any Company Payments shall be automatically reduced to an amount one dollar less than an amount that would subject the Recipient to the Excise Tax; provided, however, that the reduction shall occur only if the reduced Company Payments received by the Recipient (after taking into account further reductions for applicable federal, state and local income, social security and other taxes) would be greater than the unreduced Company Payments to be received by the Recipient minus (i) the Excise Tax payable with respect to such Company Payments and (ii) all applicable federal, state and local income, social security and other taxes on such Company Payments. If the Company Payments are to be reduced in accordance with the foregoing, the Company Payments shall be reduced as mutually agreed between the Employer and the Recipient or, in the event the parties cannot agree, in the following order: (1) acceleration of vesting of any option where the exercise price exceeds the fair market value of the underlying shares at the time the acceleration would otherwise occur; (2) any lump-sum severance based on a multiple of base salary or bonus; (3) any other cash amounts payable to the Recipient; (4) any benefits valued as parachute payments; and (5) acceleration of vesting of any equity not covered by (1) above.

(c) Unless a later delivery date is elected by the Recipient at a time and in a manner which complies with the requirements of Section 409A of the Code (and the regulations thereunder), shares of Company Stock issuable pursuant to the vesting of Restricted Stock Units shall be delivered on the earlier of (1) the termination of the Recipient's employment, (2) the seventh anniversary of the date of grant of the Restricted Stock Units and (3) the date of a Change in Control (provided that the shares of Company Stock may be delivered upon such Change in Control without violating Section 409A of the Code).

3. **Termination of Service**. Subject to the terms of the Plan and Section 2(b) hereof, if the Recipient's employment with the Company is terminated for any reason (other than as set forth in Section 2(b) hereof and as a result of Recipient's retirement on the terms set forth below or death), the Recipient shall forfeit any or all of the shares of Company Stock subject to the Restricted Stock Unit that have not vested in accordance with Section 2 hereof. Notwithstanding the preceding sentence, upon the Recipient's retirement (as defined in the Company's employee handbook as in effect on the date hereof), the Restricted Stock Units granted to the Recipient shall continue to vest in installments as provided in the *Notice of Grant of Restricted Stock Units* as if the Recipient had continued to be employed by or provide services to the Employer. The Restricted Stock Units shall become fully vested as of the date of death of the Recipient, provided that the Recipient is employed by the Employer on the date of his/her death.

4. **Securities Laws Requirements**. The Company shall not be obligated to transfer any shares of Company Stock to the Recipient, if such transfer, in the opinion of counsel for the Company, would violate the Securities Act (or any other federal or state statutes having similar requirements as may be in effect at that time).

5. **Invalid Transfers**. No purported sale, assignment, mortgage, hypothecation, transfer, pledge, encumbrance, gift, transfer in trust (voting or other) or other disposition of, or creation of a security interest in or lien on, any of the Restricted Stock Units by any holder thereof in violation of the provisions of this Agreement or the Certificate of Incorporation or the By-Laws of the Company shall be valid. The foregoing restrictions are in addition to and not in lieu of any other remedies, legal or equitable, available to enforce said provisions.

6. **Taxes**. At the time the Recipient recognizes taxable income in respect of the Restricted Stock Units, an amount equal to the federal, state and/or local taxes the Company determines it is required to withhold under applicable tax laws with respect to the Restricted Stock Units shall be due from the Recipient to the Company and shall (except as may otherwise be determined by the Board of Directors or the Committee from time to time (including following the date hereof)) be satisfied by surrendering to the Company a portion of the shares of Company Stock otherwise deliverable with respect to the Restricted Stock Units the vesting of which gives rise to the withholding obligation (but only to the extent of the minimum withholding required by law). Shares so surrendered by the Recipient shall be credited against any such withholding obligation at the Fair Market Value of

such shares on the date of such vesting (and the amount equal to the Fair Market Value of such shares shall be remitted by the Company to the appropriate tax authorities). The Recipient understands that he or she (and not the Company) shall be responsible for any tax liability that may arise as a result of the transactions contemplated by this Agreement.

7. **Rights as a Shareholder**. The Recipient will not have the rights of a shareholder with respect to shares of Company Stock subject to the Restricted Stock Units until the vesting of the Restricted Stock Units and the delivery of shares of Company Stock with respect to such vesting. To the extent that the Company declares a cash dividend while all or a portion of the Restricted Stock Units are unvested, the Recipient shall be credited with dividend equivalent rights with respect to each share of Company Stock subject to the unvested portion of the Restricted Stock Units. Such dividend equivalent right will entitle the Recipient to payment of such dividend only upon vesting of the corresponding portion of the Restricted Stock Unit; and such right will be forfeited to the extent the corresponding portion of the Restricted Stock Unit is forfeited. The Company may, in its sole discretion, determine to deliver any documents related to participation in the Plan or deliverable to the Recipient in the Recipient's capacity as a shareholder of the Company by electronic means. The Recipient hereby consents to receive any and all such documents by electronic delivery to the extent the Company utilizes such delivery method from time to time.

8. **Compliance with Law and Regulations**. This Agreement, the award hereunder and any obligation of the Company hereunder shall be subject to all applicable federal, state and local laws, rules and regulations and to such approvals by any government or regulatory agency as may be required. Except to the extent preempted by any federal law, this Agreement shall be construed and administered in accordance with the laws of the State of New York without reference to its principles of conflicts of law.

9. **Recipient Bound by Plan**. The Recipient acknowledges receipt of a copy of this Agreement and the Plan and agrees to be bound by all the terms and provisions thereof, which are incorporated herein by reference. To the extent that this Agreement is silent with respect to, or in any way inconsistent with, the terms of the Plan, the provisions of the Plan shall govern and this Agreement shall be deemed to be modified accordingly.

10. **Notices**. Any notice or communication given hereunder shall be in writing and shall be deemed given when delivered in person, or by United States mail, at the following addresses: (i) if to the Company, to: Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, Attention: Secretary, and (ii) if to the Recipient, to: the Recipient at Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, or, if the Recipient has terminated service with the Company, to the last address for the Recipient indicated in the records of the Company, or such other address as the relevant party shall specify at any time hereafter in accordance with this Section 10.

11. **No Obligation to Continue Employment**. This Agreement does not guarantee that the Employer will employ the Recipient for any specified time period, nor does it modify in any respect the Recipient's employment or compensation.

12. **Recoupment**. By entering into this Agreement and accepting the award hereunder, the Recipient agrees to be bound by the terms of the Company's Policy Regarding Recoupment or Reduction of Incentive Compensation for Compliance Violations, as in effect from time to time (or any successor policy thereto) (the "Recoupment Policy"), and further acknowledges and agrees that the Recoupment Policy shall apply to the Restricted Stock Units and the shares of Company Stock deliverable pursuant to the Restricted Stock Units granted hereunder (including after all restrictions on such shares have lapsed).

Regeneron Pharmaceuticals, Inc.
ID: [ ]
777 Old Saw Mill River Road
Tarrytown, New York 10591

Notice of Grant of Stock Options and Option Agreement

[OPTIONEE NAME]
[OPTIONEE ADDRESS]

Option Number: [ ]
Plan: [ ]
ID: [ ]

Effective <date> (the "Grant Date") you have been granted a Non-Qualified Option to buy [ ] shares of Regeneron Pharmaceuticals, Inc. (the "Company") stock at $[ ] per share.

The total option price of the shares granted is $[ ].

Full Vest Dates: This option will vest and become exercisable (i) on the date of the Company's [ ]* Annual Meeting of Shareholders with respect to a pro-rata portion of the total number of shares underlying the option equal to the portion of one year that has elapsed from the date of grant to the date of the Company's [ ]* Annual Meeting of Shareholders, and (ii) on [/ /]** with respect to the remainder of the shares underlying the option. Assuming the [ ]* Annual Meeting of Shareholders occurs on [/ /] as currently planned, this option will vest and become exercisable with respect to [ ] underlying shares on [/ /] and with respect to [ ] underlying shares on [/ /]**.

You and the Company agree that these options are granted under and governed by the terms and conditions of the Second Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long Term Incentive Plan, as amended from time to time, and the enclosed Option Agreement, both of which are attached and made a part of this document.

* The next Annual Meeting of Shareholders following the Grant Date.

** First anniversary of the Grant Date.

REGENERON PHARMACEUTICALS, INC.

Non-Qualified Stock Option

OPTION AGREEMENT
PURSUANT TO
THE SECOND AMENDED AND RESTATED REGENERON PHARMACEUTICALS, INC.
2014 LONG-TERM INCENTIVE PLAN
(Non-Employee Director Grant)

THIS AGREEMENT (this "Agreement"), made as of the date of the *Notice of Grant of Stock Options*, by and between Regeneron Pharmaceuticals, Inc., a New York corporation (the "Company"), and the individual named on the *Notice of Grant of Stock Options* (the "Grantee"). Any capitalized term used but not defined in this Agreement shall have the meaning given to such term in the Plan (as defined below).

WHEREAS, the Grantee is a non-employee member of the board of directors of the Company (the "Board") and the Company desires to afford the Grantee the opportunity to acquire or enlarge the Grantee's stock ownership in the Company so that the Grantee may have a direct proprietary interest in the Company's success; and

WHEREAS, the Committee administering the Second Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (as amended from time to time, the "Plan") has granted (as of the effective date of grant specified in the *Notice of Grant of Stock Options*) to the Grantee a Stock Option to purchase the number of shares of the Company's common stock, $0.001 par value per share (the "Common Stock"), as set forth in the *Notice of Grant of Stock Options*.

NOW, THEREFORE, in consideration of the covenants and agreements herein contained, the parties agree as follows:

1. Grant of Award. Pursuant to Section 12 of the Plan, the Company grants to the Grantee, subject to the terms and conditions of the Plan and subject further to the terms and conditions set forth herein, the option (the "Option") to purchase from the Company all or any part of an aggregate of shares of Common Stock at the purchase price per share as shown on the *Notice of Grant of Stock Options*. No part of the Option granted hereby is intended to qualify as an Incentive Stock Option under Section 422 of the Internal Revenue Code of 1986, as amended (the "Code").

2. Vesting; Exercise. (a) The Option becomes exercisable in installments as provided on the *Notice of Grant of Stock Options*. To the extent that the Option has become exercisable with respect to the number of shares of Common Stock as provided on the *Notice of Grant of Stock Options* and subject to the terms and conditions of the Plan, including without limitation, Section 7(c)(2) of the Plan, the Option may thereafter be exercised by the Grantee, in whole or in part, at any time or from time to time prior to the expiration of the Option in accordance with the requirements set forth in Section 7(c)(3) of the Plan, including, without limitation, the filing of such written form of exercise notice as may be provided by the Company, and in accordance with applicable tax and other laws. In addition to the methods of payment described in Section 7(c)(3) of the Plan, the Grantee shall be eligible to pay for shares of Common Stock purchased upon the exercise of the Option by directing the Company to withhold shares of Common Stock that would otherwise be issued pursuant to the Option exercise having an aggregate Fair Market Value (as measured on the date of exercise) equal to the aggregate Option exercise price due upon such exercise. The Grantee acknowledges that it is the Grantee's responsibility to satisfy any federal, state and local tax requirements related to the exercise of the Option.

(b) The *Notice of Grant of Stock Options* indicates each date upon which the Grantee shall become entitled to exercise the Option with respect to the number of shares of Common Stock granted as indicated provided that (except as set forth below with respect to Retirement or the Grantee's death) the Grantee has not incurred a termination of service as a member of the Board prior to such date. There shall be no proportionate or partial vesting in the periods between the Full Vest Dates specified in the *Notice of Grant of Stock Options* and all vesting shall occur only on such Full Vest Dates. Except as otherwise provided below or in the *Notice of Grant of Stock Options* or as may be otherwise determined by the Committee in accordance with Section 12(e) of the Plan, no vesting shall occur after such date as the Grantee ceases to be on the Board and the entire unvested portion of the Option shall be forfeited at such time. Notwithstanding the preceding sentence, upon the Grantee's Retirement from service on the Board, the Option shall continue to vest in installments as provided on the *Notice of Grant of Stock Options* as if the Grantee had remained in service on the Board. For purposes of this Agreement, "Retirement" shall mean a voluntary termination of service on the Board (including by not standing for re-election) by the Grantee at a time when the Grantee meets both of the following criteria: the Grantee has served as a member of the Board for a minimum of three (3) years, and the combination of the Grantee's age and total years of service as a member of the Board equals a minimum of 80.

(c) Notwithstanding anything herein or in the *Notice of Grant of Stock Options* to the contrary, the Option shall be fully vested on the date of the Grantee's death if the Grantee's service on the Board has not terminated prior to the Grantee's death. In addition, and also notwithstanding anything herein (except the following sentence) or in the *Notice of Grant of Stock Options* to the contrary, the Option shall be fully vested on the date of a Change in Control if the Grantee's service on the Board has not terminated prior to such date. If the application of the provision in the foregoing sentence, similar provisions in other stock option or restricted stock grants, and other payments and benefits payable to the Grantee in connection with a Change in Control (collectively, the "Company Payments") would result in the Grantee being subject to the excise tax payable under Section 4999 of the Code (the "Excise Tax"), the amount of any Company Payments shall be automatically reduced to an amount one dollar less than an amount that would subject the Grantee to the Excise Tax; provided, however, that the reduction shall occur only if the reduced Company Payments received by the Grantee (after taking into account further reductions for applicable federal, state and local income, social security and other taxes) would be greater than the unreduced Company Payments to be received by the Grantee minus (i) the Excise Tax payable with respect to such Company Payments and (ii) all applicable federal, state and local income, social security and other taxes on such Company Payments. If the Company Payments are to be reduced in accordance with the foregoing, the Company Payments shall be reduced as mutually agreed between the Company and the Grantee or, in the event the parties cannot agree, in the following order: (1) acceleration of vesting of any option where the exercise price exceeds the fair market value of the underlying shares at the time the acceleration would otherwise occur; (2) any lump-sum severance based on a multiple of base salary or bonus; (3) any other cash amounts payable to the Grantee; (4) any benefits valued as parachute payments; and (5) acceleration of vesting of any equity not covered by (1) above.

3. Option Term. Except as otherwise provided in the next sentence or in the Plan, the Option shall expire on the tenth anniversary of the grant of the Option as shown on the *Notice of Grant of Stock Options*. In the event of termination of service as a member of the Board of the Company, except as may be otherwise determined by the Committee in accordance with Section 12(e) of the Plan, the vested portion of the Option shall expire on the earlier of (i) the tenth anniversary of this grant, or (ii)(A) subject to (D) below, three months after such termination if such termination is for any reason other than death, Retirement, or long-term disability, (B) the tenth anniversary of this grant if such termination is due to Retirement or death, (C) one year after the termination if such termination is due to the Grantee's long-term disability or (D) one year after such termination if such termination is at any time within two years after the occurrence of a Change in Control and is not due to death, Retirement, or long-term disability. For the avoidance of doubt, any outstanding and unvested portion of the Option that has become fully vested as a result of termination of the Grantee's service on the Board on account of the Grantee's death pursuant to Section 2(c) of this Agreement shall expire on the tenth anniversary of this grant.

4. Restrictions on Transfer of Option. The Option granted hereby shall not be transferable other than by will or by the laws of descent and distribution. During the lifetime of the Grantee, this Option shall be exercisable only by the Grantee. In addition, except as otherwise provided in this Agreement, the Option shall not be assigned, negotiated, pledged or hypothecated in any way (whether by operation of law or otherwise), and the Option shall not be subject to execution, attachment or similar process. Upon any other attempt to transfer, assign, negotiate, pledge or hypothecate the Option, or in the event of any levy upon the option by reason of any execution, attachment, or similar process contrary to the provisions hereof, the Option shall immediately become null and void. Notwithstanding the foregoing provisions of this Section 4, subject to the approval of the Committee in its sole and absolute discretion and to any conditions that the Committee may prescribe, the Grantee may, upon providing written notice to the Company, elect to transfer the Option to members of his or her immediate family, including, but not limited to, children, grandchildren and spouse or to trusts for the benefit of such immediate family members or to partnerships in which such family members are the only partners; provided, however, that no such transfer may be made in exchange for consideration.

5. Rights of a Shareholder. The Grantee shall have no rights as a shareholder with respect to any shares of Common Stock subject to this Option prior to the date of issuance to the Grantee of a certificate or certificates or book-entry registration or registrations for such shares. Except as provided in Section 3(c) of the Plan, no adjustment shall be made for dividends in cash or other property, distributions, or other rights with respect to such shares for which the record date is prior to the date upon which the Grantee shall become the holder of record therefor. The Company may, in its sole discretion, determine to deliver any documents related to participation in the Plan or deliverable to the Grantee in the Grantee's capacity as a shareholder of the Company by electronic means. The Grantee hereby consents to receive any and all such documents by electronic delivery to the extent the Company utilizes such delivery method from time to time.

6. Compliance with Law and Regulations. This Agreement, the award hereunder and any obligation of the Company hereunder shall be subject to all applicable federal, state and local laws, rules and regulations and to such approvals by any government or regulatory agency as may be required. The Company shall be under no obligation to effect the registration pursuant to federal securities laws of any interests in the Plan or any shares of Common Stock to be issued hereunder or to effect similar compliance under any state laws. The Company shall not be obligated to cause to be issued or delivered any certificates or register book entries evidencing shares of Common Stock pursuant to this Agreement unless and

until the Company is advised by its counsel that the issuance and delivery of such certificates or the registration of such book entries is in compliance with all applicable laws, regulations of governmental authority and the requirements of any securities exchange on which shares of Common Stock are traded. The Committee may require, as a condition of the issuance and delivery of certificates or the registration of book entries evidencing shares of Common Stock pursuant to the terms hereof, that the recipient of such shares make such agreements and representations, and that such certificates and book entries bear or be subject to such legends, as the Committee, in its sole discretion, deems necessary or desirable. Except to the extent preempted by any applicable federal law, this Agreement shall be construed and administered in accordance with the laws of the State of New York without reference to its principles of conflicts of law.

7. Grantee Bound by Plan. The Grantee acknowledges receipt of a copy of the Plan and agrees to be bound by all the terms and provisions thereof, which are incorporated herein by reference. To the extent that this Agreement is silent with respect to, or in any way inconsistent with, the terms of the Plan, the provisions of the Plan shall govern and this Agreement shall be deemed to be modified accordingly.

8. Notices. Any notice or communication given hereunder shall be in writing and shall be deemed given when delivered in person, or by United States mail, at the following addresses: (i) if to the Company, to: Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, Attention: Secretary, and (ii) if to the Grantee, to: the Grantee at Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, or, if the Grantee has terminated service, to the last address for the Grantee indicated in the records of the Company, or such other address as the relevant party shall specify at any time hereafter in accordance with this Section 8.

Regeneron Pharmaceuticals, Inc.

ID: [ ]

777 Old Saw Mill River Road

Tarrytown, New York 10591

Notice of Grant of Restricted Stock Units and Restricted Stock Unit Agreement

[NAME]

[ADDRESS]

RSU Number: **[ ]**

Plan: **[ ]**

ID: **[ ]**

Effective <date> (the "Grant Date") you have been granted restricted stock units with respect to [ ] shares of Regeneron Pharmaceuticals, Inc. (the "Company") stock.

The total current value of the award is $[ ].

Full Vest Dates: These restricted stock units will vest (i) on the date of the Company's [ ]* Annual Meeting of Shareholders with respect to a pro-rata portion of the total number of shares underlying the award equal to the portion of one year that has elapsed from the date of grant to the date of the Company's [ ]* Annual Meeting of Shareholders, and (ii) on [/ /]** with respect to the remainder of the shares underlying the award. Assuming the [ ]* Annual Meeting of Shareholders occurs on [/ /] as currently planned, these restricted stock units will vest respect to [ ] underlying shares on [/ /] and with respect to [ ] underlying shares on [/ /]**. Vested restricted stock units remain subject to the tax deferral provisions set forth in the enclosed Restricted Stock Unit Agreement.

You and the Company agree that these restricted stock units are granted under and governed by the terms and conditions of the Second Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long Term Incentive Plan, as amended from time to time, and the enclosed Restricted Stock Unit Agreement, both of which are attached and made a part of this document.

* The next Annual Meeting of Shareholders following the Grant Date.

** First anniversary of the Grant Date.

REGENERON PHARMACEUTICALS, INC.

RESTRICTED STOCK UNIT AGREEMENT
PURSUANT TO
THE SECOND AMENDED AND RESTATED REGENERON PHARMACEUTICALS, INC.
2014 LONG-TERM INCENTIVE PLAN

THIS AGREEMENT (this "Agreement"), made as of the date on the *Notice of Grant of Restricted Stock Units*, by and between Regeneron Pharmaceuticals, Inc., a New York corporation (the "Company"), and the individual named on the *Notice of Grant of Restricted Stock Units* (the "Recipient"). Any capitalized term used but not defined in this Agreement shall have the meaning given to such term in the Plan (as defined below).

WHEREAS, the Recipient is a non-employee member of the board of directors of the Company (the "Board") and the Company desires to afford the Recipient the opportunity to acquire or enlarge the Recipient's stock ownership in the Company so that the Recipient may have a direct proprietary interest in the Company's success; and

WHEREAS, the Committee administering the Second Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (as amended from time to time, the "Plan") has granted (as of the effective date of grant specified in the *Notice of Grant of Restricted Stock Units*) to the Recipient a Restricted Stock Unit (as defined below) with respect to the number of shares of Company Stock as set forth in the *Notice of Grant of Restricted Stock Units*.

NOW, THEREFORE, in consideration of the covenants and agreements herein contained, the parties agree as follows:

1. **Grant of Award**. Pursuant to Section 9 of the Plan, the Company grants to the Recipient, subject to the terms and conditions of the Plan and subject further to the terms and conditions set forth herein, a restricted stock unit (referred to in the Plan as "Phantom Stock") (each such unit, a "Restricted Stock Unit") with respect to the number of shares of Company Stock as shown on the Notice of Grant of Restricted Stock Units. The Recipient's record of Company Stock ownership shall be recorded in the books of the Company only when the Restricted Stock Units vest and the shares of Company Stock are issued. At the Recipient's request, vested shares may be evidenced by stock certificates or book-entry registration.

2. **Vesting; Delivery**. (a) The Restricted Stock Units granted to the Recipient shall vest in installments as provided in the Notice of Grant of Restricted Stock Units. The vesting schedule in the Notice of Grant of Restricted Stock Units indicates each date upon which the Restricted Stock Units shall vest, entitling the Recipient to receive the underlying shares of Company Stock, provided that the Recipient has not incurred a termination of service as a member of the Board. There shall be no proportionate or partial vesting in the periods between the Full Vest Dates specified in the Notice of Grant of Restricted Stock Units and all vesting shall occur only on such Full Vest Dates. No vesting shall occur after the termination of the Recipient's service as a member of the Board for any reason. Notwithstanding the preceding sentence, upon the Recipient's Retirement from service on the Board, the Restricted Stock Units shall continue to vest in installments as provided on the Notice of Grant of Restricted Stock Units as if the Recipient had remained in service on the Board. For purposes of this Agreement, "Retirement" shall mean a voluntary termination of service on the Board (including by not standing for re-election) by the Recipient at a time when the Recipient meets both of the following criteria: the Recipient has served as a member of the Board for a minimum of three (3) years, and the combination of the Recipient's age and total years of service as a member of the Board equals a minimum of 80.

(b) Notwithstanding anything herein (except the following sentence) or in the Notice of Grant of Restricted Stock Units to the contrary, outstanding Restricted Stock Units granted to Recipient shall be fully vested on the date of a Change in Control or upon the Recipient's death. If the application of the provision in the foregoing sentence, similar provisions in other stock option or equity compensation grants, and other payments and benefits payable to the Recipient (collectively, the "Company Payments") would result in the Recipient being subject to excise tax (the "Excise Tax") payable under Section 4999 of the Internal Revenue Code of 1986, as

amended (the "Code"), the amount of any Company Payments shall be automatically reduced to an amount one dollar less than an amount that would subject the Recipient to the Excise Tax; provided, however, that the reduction shall occur only if the reduced Company Payments received by the Recipient (after taking into account further reductions for applicable federal, state and local income, social security and other taxes) would be greater than the unreduced Company Payments to be received by the Recipient minus (i) the Excise Tax payable with respect to such Company Payments and (ii) all applicable federal, tate and local income, ocial ecurity and other taxe on uch Company Payment If the Company Payment are to be reduced in accordance with the foregoing, the Company Payments shall be reduced as mutually agreed between the Company and the Recipient or, in the event the parties cannot agree, in the following order: (1) acceleration of vesting of any option where the exercise price exceeds the fair market value of the underlying shares at the time the acceleration would otherwise occur; (2) any lump-sum severance based on a multiple of base salary or bonus; (3) any other cash amounts payable to the Recipient; (4) any benefits valued as parachute payments; and (5) acceleration of vesting of any equity not covered by (1) above

(c) Unless a later delivery date is elected by the Recipient at a time and in a manner which complies with the requirements of Section 409A of the Code (and the regulations thereunder), shares of Company Stock issuable pursuant to the vesting of Restricted Stock Units shall be delivered on the earlier of (1) the termination of the Recipient's service as a member of the Board, (2) the seventh anniversary of the date of grant of the Restricted Stock Unit and (3) the date of a Change in Control (provided that the hare of Company Stock may be delivered upon uch Chan e in Control without violating Section 409A of the Code). With respect to Restricted Stock Units which become vested following termination of the Recipient's service as a member of the Board pursuant to the last two sentences of Section 2(a), shares of Company Stock with respect thereto shall be delivered as soon as practicable following vesting, unless a later delivery date is elected by the Recipient at a time and in a manner which complies with the requirements of Section 409A of the Code (and the regulations thereunder).

3. **Termination of Service**. Subject to the terms of the Plan and Section 2 hereof, if the Recipient's service on the Board is terminated for any reason (other than as set forth in Section 2 hereof), the Recipient shall forfeit any or all of the shares of Company Stock subject to the Restricted Stock Unit that have not vested in accordance with Section 2 hereof.

4. **Securities Laws Requirements**. The Company shall not be obligated to transfer any shares of Company Stock to the Recipient, if such transfer, in the opinion of counsel for the Company, would violate the Securities Act (or any other federal or state statutes having similar requirements as may be in effect at that time).

5. **Invalid Transfers**. No purported sale, assignment, mortgage, hypothecation, transfer, pledge, encumbrance, gift, transfer in trust (voting or other) or other disposition of, or creation of a security interest in or lien on, any of the Restricted Stock Units by any holder thereof in violation of the provi ion of thi A reement or the Certificate of Incorporation or the By Law of the Company shall be valid The fore oing re triction are in addition to and not in lieu of any other remedies, legal or equitable, available to enforce said provisions.

6 **Right a a Shareholder** The Recipient will not have the ri ht of a shareholder with re pect to hare of Company Stock subject to the Restricted Stock Units until the vesting of the Restricted Stock Units and the delivery of shares of Company Stock with respect to such vesting. To the extent that the Company declares a cash dividend while all or a portion of the Restricted Stock Units are unvested, the Recipient shall be credited with dividend equivalent rights with respect to each share of Company Stock subject to the unvested portion of the Restricted Stock Units. Such dividend equivalent right will entitle the Recipient to payment of such dividend only upon vesting of the corresponding portion of the Restricted Stock Unit; and uch ri ht will be forfeited to the extent the corre ponding portion of the Re tricted Stock Unit i forfeited The Company may, in it ole discretion, determine to deliver any documents related to participation in the Plan or deliverable to the Recipient in the Recipient's capacity as a shareholder of the Company by electronic means. The Recipient hereby consents to receive any and all such documents by electronic delivery to the extent the Company utilizes such delivery method from time to time.

7. **Compliance with Law and Regulations**. This Agreement, the award hereunder and any obligation of the Company hereunder shall be subject to all applicable federal, state and local laws, rules and regulations and to such approvals by any government or regulatory agency as may be required. Except to the extent

preempted by any federal law, this Agreement shall be construed and administered in accordance with the laws of the State of New York without reference to its principles of conflicts of law.

8. **Recipient Bound by Plan**. The Recipient acknowledges receipt of a copy of this Agreement and the Plan and agrees to be bound by all the terms and provisions thereof, which are incorporated herein by reference. To the extent that this Agreement is silent with respect to, or in any way inconsistent with, the terms of the Plan, the provisions of the Plan shall govern and this Agreement shall be deemed to be modified accordingly.

9. **Notices**. Any notice or communication given hereunder shall be in writing and shall be deemed given when delivered in person, or by United States mail, at the following addresses: (i) if to the Company, to: Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, Attention: Secretary, and (ii) if to the Recipient, to: the Recipient at Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, or, if the Recipient has terminated service with the Company, to the last address for the Recipient indicated in the records of the Company, or such other address as the relevant party shall specify at any time hereafter in accordance with this Section 9.

REGENERON PHARMACEUTICALS, INC.
ID: 13-3444607
777 Old Saw Mill River Road
Tarrytown, NY 10591

Notice of Grant of Performance Restricted Stock Units and Performance Restricted Stock Unit Agreement ("Notice")

[NAME]	**Performance RSU Number:**	**[ ]**
[ADDRESS]	**Plan:**	**[ ]**
	ID:	**[ ]**

Effective <date>, (the "Grant Date") you have been granted Performance Restricted Stock Units with respect to a target number of [ ] shares of REGENERON PHARMACEUTICALS, INC. (the "Company") common stock (the "Target PSU"). Please refer to Section 2, Definitions below for definitions of certain terms used in this Notice. Any capitalized term used but not defined in this Notice shall have the meaning given to such term in the Plan.

1. Vesting Criteria and Rules.

A. Primary Performance Criteria.

The Performance Restricted Stock Units shall be earned and eligible to vest based on TSR (as defined below) determinations that are to be made commencing on March 15, 2021 with respect to the Threshold level of performance set forth in the table below and commencing December 31, 2023 with respect to levels above such Threshold level of performance, subject to earlier determinations upon a Change in Control and in connection with certain terminations of Service (as defined below and further described in Section 1.C. below). To the extent that Performance Restricted Stock Units do not vest on or before December 31, 2025 (the period from the Grant Date until such date, the "Performance Period") either (1) pursuant to the criteria set forth in this Section 1.A. (the "Primary Performance Criteria") or (2) pursuant to the criteria set forth in Section 1.B. (the "Secondary Performance Criteria"), such Performance Restricted Stock Units shall be forfeited on such date, subject to earlier vesting or termination pursuant to the application of the Special Vesting Rules Upon Certain Terminations and Change in Control set forth in Section 1.C.

If and to the extent earned pursuant to the Primary Performance Criteria or the Secondary Performance Criteria, the Performance Restricted Stock Units shall vest on December 31, 2025, subject to your continuous employment with the Company or service as a member of the Board of Directors or as a consultant to the Company on such date (such employment, service as a member of the Board of Directors, or service as a consultant to the Company is referred to herein as "Service"). Rules regarding

the timing of issuance of shares of Company Stock in connection with the vesting of Performance Restricted Stock Units are set forth below under Section 1.D. ("Delivery Rules").

Attainment of the Primary Performance Criteria shall be based on attainment of the price target goals set forth in the "Price Target" column of the table below (the "Price Target Goals"), which attainment shall be measured using the Ending Stock Price as compared to the Price Target Goals. The Price Target Goals shall be subject to adjustment by the Committee in its discretion for any dividends or other shareholder distributions paid with respect to Company Stock during the Performance Period, recapitalizations or similar events. The number of shares of Company Stock, if any, earned in respect of the attainment of the Primary Performance Criteria shall be determined as follows:

Primary Performance Criteria

Performance Level	Price Target	Payout in Shares (as a percentage of Target)
Maximum	**$1,150**	**250%**
	$1,079	225%
	$1,016	200%
	$956	175%
	$898	150%
	$844	125%
Target	$792	**100%**
	$706	75%
Threshold	**$628**	**50%**

No Performance Restricted Stock Units shall be earned under this Section 1.A. for performance below the Threshold performance level and no additional Performance Restricted Stock Units shall be earned for performance above the Maximum performance level. Straight line interpolation shall be applied to determine the number of Performance Restricted Stock Units earned for performance above the Threshold performance level and falling between the Price Target Goals. Following vesting, the provisions of Section 1.D. shall apply to the delivery of Company Stock earned with respect to the Performance Restricted Stock Units due to attainment of the Primary Performance Criteria.

B. Secondary Relative TSR Performance Criteria

If, at the end of the Performance Period, or following an earlier final determination of performance against the Primary Performance Criteria pursuant to Section 1.C., (a) no Performance Restricted Stock Units have been earned pursuant to Section 1.A and (b) the Company's TSR for the applicable period is at least 200 basis points above the TSR of the Nasdaq Biotech Index (composite return) for the corresponding period, then the payout corresponding to the Threshold level of performance shall be earned as of such date. Following vesting, the provisions of Section 1.D. shall apply to the delivery of Company Stock earned with respect to the Performance Restricted Stock Units due to attainment of the Secondary Relative TSR Performance Criteria.

C. Special Vesting Rules Upon Certain Terminations and Change in Control

Except as specifically set forth in this Section 1.C., any earned and unearned Performance Restricted Stock Units shall be forfeited in their entirety in the event that your Service ceases prior to the end of the Performance Period. You specifically acknowledge and agree that the provisions set forth herein with respect to termination of Service supersede any provisions of any other agreement between you and the Company or any Affiliate, including any agreement that provides a different treatment for equity awards due to death or retirement [(without limiting the generality of the foregoing, including Section 8(f) of the Amended and Restated Employment Agreement, dated as of November 14, 2008, by and between you and the Company, as in effect from time to time (the "Employment Agreement"))][1]. The following special rules shall apply to the Performance Restricted Stock Units, notwithstanding the provisions of Section 1.A. and 1.B. above.

Without Cause or for Good Reason. If your Service is terminated without Cause or you resign from your Service for a Good Reason prior to December 31, 2025, the Performance Period will be deemed to have ended upon the date of termination and an earnout determination shall be made as of the date of termination first pursuant to Section 1.A. and second, if applicable, pursuant to Section 1.B., and any earned Performance Restricted Stock Units shall immediately vest as of such date. To the extent that any Performance Restricted Stock Units remain unearned following the earnout determination described in the preceding sentence, earnout determinations shall continue to be conducted until the earlier of the first anniversary of the date of termination and December 31, 2025 and, to the extent earned, such Performance Restricted Stock Units shall vest on the earlier of the first anniversary of the date of termination and December 31, 2025. To the extent any Performance Restricted Stock Units are determined to have been earned and vested pursuant to the two preceding sentences, the provisions of Section 1.D. regarding delivery shall apply to the shares of Company Stock deliverable in respect of such Performance Restricted Stock Units. Performance Restricted Stock Units which do not vest by the first anniversary of the date of termination shall be immediately forfeited.

Change in Control. If, prior to December 31, 2025, a Change in Control occurs, the Performance Period shall be deemed to have ended immediately prior to the consummation of the Change in Control and, notwithstanding the definitions of TSR and Ending Stock Price herein, the price per share of Company Stock in the Change in Control transaction (as determined by the Committee), as adjusted for any Dividend Value, shall be used to make an earnout determination on the date of the Change in Control first pursuant to Section 1.A. and second, if applicable, pursuant to Section 1.B. All Performance Restricted Stock Units earned as of that date shall vest immediately and shall not be subject to the provisions of Section 1.D. regarding delivery and shall be delivered as soon as practicable following the earnout determination; and any unearned Performance Restricted Stock Units as of that date shall be immediately forfeited.

Death or Disability. In the case of your death or Disability prior to December 31, 2025, the Performance Restricted Stock Units shall remain outstanding and may be earned pursuant to the provisions hereof and, to the extent earned, shall vest on December 31, 2025 without regard to the continued Service requirement. To the extent earned and vested, shares deliverable pursuant to the Performance Restricted Stock Units following death or Disability shall not be subject to the provisions of Section 1.D. regarding deferred delivery and shall be delivered as soon as practicable following the vesting date.

D. Delivery Rules

[1] Only applicable to the *Notice of Grant of Performance Restricted Units* for Leonard S. Schleifer, M.D., Ph.D.

Holding Period. Shares of Company Stock deliverable in respect of earned and vested Performance Restricted Stock Units are, except as specifically set forth in Section 1.C. or this Section 1.D., subject to a mandatory deferral and holding period of three years after the applicable vesting date (the "Holding Period") and shall not be delivered until immediately following the expiration of the Holding Period. Notwithstanding the foregoing and subject to compliance with the 409A Rules set forth below, any Holding Period shall end upon your death or Disability or a Change in Control (which terms shall be interpreted in a manner that complies with the requirements of Section 409A of the Code).

2. Definitions.

"Beginning Stock Price" shall mean the price of $478.30 per share of Company Stock.

"Cause" shall mean (i) in the case where there is no employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between you and the Company (or otherwise applicable to you) on the Grant Date (or where there is such an agreement or plan but it does not define "cause" (or words of like import) or such agreement or plan would not apply) (A) the willful and continued failure by you substantially to perform your duties and obligations to the Company (other than any such failure resulting from your incapacity due to physical or mental illness), including without limitation, repeated refusal to follow the reasonable directions of the Company, violation of the Company's Code of Business Conduct and Ethics, knowing violation of law in the course of performance of your duties of employment, repeated absences from work without a reasonable excuse, or intoxication with alcohol or illegal drugs while on the Company's premises during regular business hours; (B) fraud or material dishonesty against the Company; or (C) a conviction or plea of guilty or nolo contendere to a felony or a crime involving material dishonesty; or (ii) in the case where there is an employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between you and the Company (or otherwise applicable to you) on the Grant Date that defines "cause" (or words of like import) and such agreement or plan applies, as defined under such agreement or plan. For purposes of this paragraph, no act, or failure to act, on your part shall be considered "willful" unless done, or omitted to be done, by you in bad faith and without reasonable belief that the action or omission was in the best interest of the Company.

"Closing Price" of a share of Company Stock, as of a date of determination, shall mean (1) the closing sales price per share of Company Stock on the national securities exchange or national market system on which such stock is principally traded on such date or, if such date is not a trading day, on the last preceding date on which there was a sale of such stock on such exchange, or (2) if the shares of Company Stock are not then listed on a national securities exchange or national market system, or the value of such shares is not otherwise determinable, such value as determined by the Committee in good faith.

"Disability" shall mean [a Permanent Disability as such term is defined in the Employment Agreement, provided that such termination also qualifies as][2] a termination of Service on account of a disability which meets the requirements of 1.409A-3(i)(4) of the Treasury Regulations, as determined by the Committee.

"Dividend Value" shall mean the value of any dividends paid on a share of Company Stock during the applicable measurement period, with the payment date deemed to have occurred on the ex-dividend

[2] Only applicable to the *Notice of Grant of Performance Restricted Units* for Leonard S. Schleifer, M.D., Ph.D.

date for such dividend and the amount of such dividend deemed reinvested in shares of Company Stock as of the ex-dividend date (based on the Closing Price of such shares on such date).

“Ending Stock Price” shall mean the average Closing Price of a share of Company Stock for the twenty trading days immediately preceding the applicable determination date, after adjusting for the Dividend Value, as applicable.

"Good Reason" shall mean (i) in the case where there is no employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between you and the Company (or otherwise applicable to you) on the Grant Date (or where there is such an agreement or plan but it does not define “good reason” (or words of like import) or such agreement or plan would not apply) a termination of employment by you within one hundred twenty (120) days after the occurrence of one of the following events unless such events are fully corrected in all material respects by the Company within thirty (30) days following written notification by you to the Company that you intend to terminate your employment hereunder for one of the reasons set forth below: (A) (1) any material diminution in your duties and responsibilities from those which existed as of the Grant Date (except in each case in connection with the termination of your employment for Cause or as a result of your death, or temporarily as a result of your illness or other absence), or (2) the assignment to you of duties and responsibilities materially inconsistent with the position held by you; (B) any material breach by the Company of any material provision of any written agreement with you or failure to timely pay any compensation obligation to you; (C) a reduction in your annual base salary or target bonus opportunity (if any) from that which existed as of the Grant Date; or (D) if you are based at the Company’s principal executive office, any relocation therefrom or, in any event, a relocation of your primary office of more than fifty (50) miles from the location as of the Grant Date; (ii) in the case where there is an employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between you and the Company (or otherwise applicable to you) on the Grant Date that defines “good reason” (or words of like import) and such agreement or plan applies, as defined under such agreement or plan[; provided, however, that any such definition shall be deemed, solely for purposes of this Notice, to include as one of the reasons that the employment of Leonard S. Schleifer, M.D., Ph.D. with the Company under the Amended and Restated Employment Agreement, dated as of November 14, 2008, by and between Dr. Schleifer and the Company, as in effect from time to time (the “Employment Agreement”), has ended due to Dr. Schleifer’s Involuntary Termination (as defined in the Employment Agreement)][3]; or (iii) at a time when you are no longer employed by the Company because your employment has been terminated without Cause or you have resigned from your employment for a reason specified in clause (i) or clause (ii) of this definition of “Good Reason” but your Service continues because you serve as a member of the Board of Directors or a consultant to the Company, your voluntary resignation or other termination of your service as a member of the Board of Directors or voluntary resignation or termination of your service as a consultant (as applicable).

“Plan” shall mean the Second Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan, as amended from time to time.

“TSR” shall mean the percent return on a share of Company Stock, determined using the following calculation:

TSR = (Ending Stock Price - Beginning Stock Price)/(Beginning Stock Price)

[3] Only applicable to the *Notice of Grant of Performance Restricted Units* for George D. Yancopoulos, M.D., Ph.D.

3. Special Rules.

For the avoidance of doubt, and notwithstanding any provision in this Notice, the Performance Restricted Stock Unit Agreement, or the Plan to the contrary, no termination of Service shall be deemed to take place unless you cease both to be employed by and to provide service to the Company and/or its Subsidiaries as a consultant or as a member of the Board of Directors. In addition, to the extent necessary to comply with the requirements of Section 409A of the Code, no termination shall be deemed to occur unless the termination constitutes a "separation from service" for purposes of Section 409A of the Code.

In the event that the Company pays dividends during the Performance Period, the number of shares of Company Stock subject to the Target PSU shall be increased by a number of shares of Company Stock equal to the aggregate amount of the dividend payable with respect to the number of shares of Company Stock subject to the Target PSU, divided by the Fair Market Value of a share of the Company Stock on the ex-dividend date with respect to such dividend.

Shares of Company Stock earned and vested pursuant to the Performance Restricted Stock Unit Agreement and this Notice shall be delivered (subject to satisfaction of the applicable tax withholding requirements) as soon as practicable (but in no event more than 30 days) following either the end of the Holding Period or the applicable vesting date, as applicable.

You and the Company agree that these Performance Restricted Stock Units are granted under and governed by the terms and conditions of the Plan and the enclosed Performance Restricted Stock Unit Agreement, both of which are attached and made a part of this document.

409A Rules. The Performance Restricted Stock Units are intended to comply with the requirements of Section 409A of the Code and shall be administered and interpreted in a manner consistent with this intent. If the Company determines that this award is subject to Section 409A of the Code and that it does not comply with or is inconsistent with the applicable requirements, the Company may, in its sole discretion, and without your consent, amend this award to cause it to comply with Section 409A of the Code. Notwithstanding any provision of this award to the contrary, in the event that any settlement of the Performance Restricted Stock Units occurs as a result of your termination of employment and the Company determines that you are a “specified employee” (within the meaning of Section 409A of the Code) subject to Section 409A of the Code at the time of your termination of employment, and provided further that such settlement does not otherwise qualify for an applicable exemption from Section 409A of the Code, then no such settlement shall occur until the date that is the earlier to occur of: (i) your death, or (ii) six (6) months and one (1) day following your termination of employment. To the extent necessary to comply with Section 409A of the Code, the terms “Retirement,” “terminate,” “termination,” “termination of employment,” termination of Service, and variations thereof as used in this Award Agreement are intended to mean a “separation from service” as such term is defined under Section 409A of the Code. Although this award is intended to comply with the requirements of Section 409A of the Code, the Company does not represent or warrant that this award or the payments provided hereunder will comply with Section 409A of the Code or any other provisions of federal, state, local, or non-U.S. law. The Company shall not be liable to you (or any other individual claiming a benefit through you) for any tax, interest, or penalties you may owe as a result of compensation paid under this award, and the Company shall have no obligation to indemnify or otherwise protect you from the obligation to pay any taxes pursuant to Section 409A of the Code. Each payment of shares of Company Stock hereunder shall be considered a separate payment for purposes of Code Section 409A.

REGENERON PHARMACEUTICALS, INC.

PERFORMANCE RESTRICTED STOCK UNIT AGREEMENT
PURSUANT TO
THE SECOND AMENDED AND RESTATED REGENERON PHARMACEUTICALS, INC.
2014 LONG-TERM INCENTIVE PLAN

THIS AGREEMENT (this "Agreement"), made as of the date on the *Notice of Grant of Performance Restricted Stock Units*, by and between Regeneron Pharmaceuticals, Inc., a New York corporation (the "Company" and, together with its Subsidiaries, the "Employer"), and the employee named on the *Notice of Grant of Performance Restricted Stock Units* (the "Recipient"). Any capitalized term used but not defined in this Agreement shall have the meaning given to such term in the Plan (as defined below).

WHEREAS, the Recipient is an employee of the Company (or a Subsidiary of the Company) and the Company desires to afford the Recipient the opportunity to acquire or enlarge the Recipient's stock ownership in the Company so that the Recipient may have a direct proprietary interest in the Company's success; and

WHEREAS, the Committee administering the Second Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (as amended from time to time, the "Plan") has granted (as of the effective date of grant specified in the *Notice of Grant of Performance Restricted Stock Units*) to the Recipient a Performance Restricted Stock Unit (as defined below) with respect to the number of shares of Company Stock as set forth in the *Notice of Grant of Performance Restricted Stock Units*.

NOW, THEREFORE, in consideration of the covenants and agreements herein contained, the parties agree as follows:

1. **Grant of Award**. Pursuant to Section 9 of the Plan, the Company grants to the Recipient, subject to the terms and conditions of the Plan and subject further to the terms and conditions set forth herein, a restricted stock unit (referred to in the Plan as "Phantom Stock") (each such unit, a "Performance Restricted Stock Unit") with respect to the number of shares of Company Stock as determined in accordance with the *Notice of Grant of Performance Restricted Stock Units*. The Recipient's record of Company Stock ownership shall be recorded in the books of the Company only when and to the extent the Performance Restricted Stock Units vest and the shares of Company Stock are issued. At the Recipient's request, vested shares that have been issued may be evidenced by stock certificates or book-entry registration.

2. **Vesting; Forfeiture**. (a) The Performance Restricted Stock Units granted to the Recipient shall vest or be forfeited as provided in the *Notice of Grant of Performance Restricted Stock Units*. The provisions of this Section 2(a) are subject to the provisions set forth in the *Notice of Grant of Performance Restricted Stock Units* and the Recipient acknowledges and agrees that except as specifically set forth in Section 2(b) of this Agreement with respect to potential excise tax, the provisions of this agreement and the *Notice of Grant of Performance Restricted Stock Units* supersede any contradictory provisions contained in any employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Recipient (or otherwise applicable to the Recipient) on the date of grant specified in the *Notice of Grant of Performance Restricted Stock Units* [(without limiting the generality of the foregoing, the Recipient acknowledges and agrees that the provisions of this Agreement and the *Notice of Grant of Performance Restricted Units* supersede Section 8(f) of the Amended and Restated Employment Agreement, dated as of November 14, 2008, by and between the Recipient and the Company, as in effect from time to time)][4].

(b) Except as otherwise provided in any employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Recipient (or otherwise applicable to the Recipient) on the date of grant specified in the *Notice of Grant of Performance Restricted Stock Units*, if the application of the Change in Control provisions set forth in the *Notice of Grant of*

[4] Only applicable to the Performance Restricted Stock Unit Agreements for Leonard S. Schleifer, M.D., Ph.D.

Performance Restricted Stock Units, similar provisions in other stock option or equity compensation grants, and other payments and benefits payable to the Recipient upon termination of employment with the Employer or otherwise (collectively, the "Company Payments") would result in the Recipient being subject to excise tax (the "Excise Tax") payable under Section 4999 of the Internal Revenue Code of 1986, as amended (the "Code"), the amount of any Company Payments shall be automatically reduced to an amount one dollar less than an amount that would subject the Recipient to the Excise Tax; provided, however, that the reduction shall occur only if the reduced Company Payments received by the Recipient (after taking into account further reductions for applicable federal, state and local income, social security and other taxes) would be greater than the unreduced Company Payments to be received by the Recipient minus (i) the Excise Tax payable with respect to such Company Payments and (ii) all applicable federal, state and local income, social security and other taxes on such Company Payments. If the Company Payments are to be reduced in accordance with the foregoing, the Company Payments shall be reduced as mutually agreed between the Employer and the Recipient or, in the event the parties cannot agree, in the following order: (1) acceleration of vesting of any option where the exercise price exceeds the fair market value of the underlying shares at the time the acceleration would otherwise occur; (2) any lump-sum severance based on a multiple of base salary or bonus; (3) any other cash amounts payable to the Recipient; (4) any benefits valued as parachute payments; and (5) acceleration of vesting of any equity not covered by (1) above.

3. **Recipient Acknowledgement.** The Recipient hereby acknowledges and agrees that it is the mutual intent of that Recipient and the Company that the award of Performance Restricted Stock Units made pursuant to this Agreement shall be in lieu of any equity, equity-based or other long-term incentive award, in each case for the five-year period commencing on the date hereof and ending on the date on which the Company grants annual equity awards in respect of 2025 and that the Recipient shall have no entitlement for any such awards during that five-year period, whether or not any portion of the award of Performance Restricted Stock Units made pursuant to this Agreement is earned.

4. **Securities Laws Requirements**. The Company shall not be obligated to transfer any shares of Company Stock to the Recipient, if such transfer, in the opinion of counsel for the Company, would violate the Securities Act (or any other federal or state statutes having similar requirements as may be in effect at that time).

5. **Invalid Transfers**. No purported sale, assignment, mortgage, hypothecation, transfer, pledge, encumbrance, gift, transfer in trust (voting or other) or other disposition of, or creation of a security interest in or lien on, any of the Performance Restricted Stock Units by any holder thereof in violation of the provisions of this Agreement or the Certificate of Incorporation or the By-Laws of the Company shall be valid. The foregoing restrictions are in addition to and not in lieu of any other remedies, legal or equitable, available to enforce said provisions.

6. **Taxes**. At the time the Recipient recognizes taxable income in respect of the Performance Restricted Stock Units, an amount equal to the federal, state and/or local taxes the Company determines it is required to withhold under applicable tax laws with respect to the Performance Restricted Stock Units shall be due from the Recipient to the Company and shall (except as may otherwise be determined by the Board of Directors or the Committee from time to time (including following the date hereof)) be satisfied by surrendering to the Company a portion of the shares of Company Stock otherwise deliverable with respect to the Performance Restricted Stock Units the vesting of which gives rise to the withholding obligation (but only to the extent of the minimum withholding required by law). Shares so surrendered by the Recipient shall be credited against any such withholding obligation at the Fair Market Value of such shares on the date of such vesting (and the amount equal to the Fair Market Value of such shares shall be remitted by the Company to the appropriate tax authorities). The Recipient understands that he or she (and not the Company) shall be responsible for any tax liability that may arise as a result of the transactions contemplated by this Agreement.

7. **Rights as a Shareholder**. The Recipient will not have the rights of a shareholder with respect to shares of Company Stock subject to the Performance Restricted Stock Units until the vesting of the Performance Restricted Stock Units and the delivery of shares of Company Stock with respect to such vesting following the expiration of the Holding Period (as defined in the *Notice of Grant of Performance Restricted Stock Units*) (if applicable). The Company may, in its sole discretion, determine to deliver any documents related to participation in the Plan or deliverable to the Recipient in the Recipient's capacity as a shareholder of the Company

by electronic means. The Recipient hereby consents to receive any and all such documents by electronic delivery to the extent the Company utilizes such delivery method from time to time.

8. **Compliance with Law and Regulations**. This Agreement, the award hereunder and any obligation of the Company hereunder shall be subject to all applicable federal, state and local laws, rules and regulations and to such approvals by any government or regulatory agency as may be required. Except to the extent preempted by any federal law, this Agreement shall be construed and administered in accordance with the laws of the State of New York without reference to its principles of conflicts of law.

9. **Recipient Bound by Plan**. The Recipient acknowledges receipt of a copy of this Agreement and the Plan and agrees to be bound by all the terms and provisions thereof, which are incorporated herein by reference. To the extent that this Agreement is silent with respect to, or in any way incon i tent with, the term of the Plan, the provi ion of the Plan shall overn and thi Agreement shall be deemed to be modified accordin ly

10. **Notices**. Any notice or communication given hereunder shall be in writing and shall be deemed given when delivered in person, or by United State mail, at the followin addre e (i) if to the Company, to Re eneron Pharmaceutical , Inc , 777 Old Saw Mill River Road, Tarrytown, NY 10591, Attention: Secretary, and (ii) if to the Recipient, to: the Recipient at Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, or, if the Recipient has terminated service with the Company, to the last address for the Recipient indicated in the records of the Company, or such other address as the relevant party shall specify at any time hereafter in accordance with this Section 10.

11. **No Obligation to Continue Employment**. This Agreement does not guarantee that the Employer will employ the Recipient for any specified time period, nor does it modify in any respect the Recipient's employment or compensation.

12 **Recoupment** By enterin into thi Agreement and acceptin the award hereunder, the Recipient a ree to be bound by the terms of the Company's Policy Regarding Recoupment or Reduction of Incentive Compensation for Compliance Violations, as in effect from time to time (or any successor policy thereto) (the "Recoupment Policy"), and further acknowledges and agrees that the Recoupment Policy shall apply to the Performance Restricted Stock Units and the shares of Company Stock deliverable pursuant to the Performance Restricted Stock Units granted hereunder (including following the expiration of the Holding Period and otherwise after all restrictions on such shares have lapsed).

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT, MARKED BY BRACKETS, WERE OMITTED BECAUSE THOSE PORTIONS ARE NOT MATERIAL AND WOULD BE COMPETITIVELY HARMFUL TO THE COMPANY IF PUBLICLY DISCLOSED.

Applied Technologies Center
315 Sigma Drive
Summerville, SC 29486
www.ati.org

PROJECT AGREEMENT NO.: 1

MCDC BASE AGREEMENT NO.: 2020-504

PROJECT TITLE: MCDC2008-005; Large-Scale Manufacturing of Antibodies Directed to SARS-CoV-2

PARTIES: Advanced Technology International ("MCDC CMF") and Regeneron Pharmaceuticals, Inc. ("Project Agreement Holder")

This Project Agreement is awarded under the authority of MCDC Base Agreement No. 2020-504, and herein incorporates all the terms and conditions thereof, as such terms and conditions are modified by the terms of the Statement Of Work attached hereto as Exhibit A (the "Statement of Work" or "SOW"). The parties agree that, to the extent any terms or conditions of the Statement of Work conflict with the terms and conditions of MCDC Base Agreement No. 2020-504, the terms and conditions of the Statement of Work shall apply and take precedence.

1. PAYMENT METHOD
The Payment Method for this Project Agreement is Firm Fixed Price with a not to exceed ceiling.

2. TERM OF THE PROJECT AGREEMENT
The period of performance for this Project Agreement is from the effective date, which is the date of the last signature through June 30, 2021.

3. OBLIGATION
The MCDC CMF's liability to make payments to the Project Agreement Holder is limited to only those funds obligated under this Project Agreement or by modification to the Project Agreement. MCDC CMF may incrementally fund this Project Agreement.

4. TOTAL FIRM FIXED PRICE
The total firm fixed price for the services to be provided by the Project Agreement Holder is as follows:

Total Firm Fixed Price $450,262,000

5. TOTAL FUNDING
The total amount of funding currently available for payment and allotted to this Project Agreement is **$450,262,000**.

6. MILESTONE PAYMENT SCHEDULE

The Project Agreement Holder shall document the accomplishments of each Project Payable Milestone under each Project Agreement. Acceptance of Milestones shall be contingent upon approval from the Government Agreements Officer Representative (AOR) detailed in Clause No. 9, Technical and Administrative Representatives. Milestone payments will be paid in the amount indicated in the attached Milestone Payment Schedule (Attachment A).

7. APPROACH TO MEETING THE OTHER TRANSACTION AUTHORITY

In accordance with provision contained in 10 USC 2371b governing the use Other Transaction Agreements each MCDC Member Organization must meet at least one of the following conditions: have at least one nontraditional defense contractor or nonprofit research institution participating to a significant extent in the performance of an awarded Project Agreement; all significant participants in the Project Agreement other than the Federal Government are small businesses (including small businesses participating in a program described under section 9 of the Small Business Act (15 U.S.C. 638)) or nontraditional defense contractors; or provide a cost share of no less than one third of the value of the Project Agreement awarded to the Member Organization. The Project Agreement Holder's approach to meeting the Other Transaction Authority requirement is identified below. Throughout the period of performance of any Project Agreement, the CMF and the Government will actively monitor the award to ensure compliance with this provision in accordance with implementation guidance from Headquarters – Department of the Army (HQDA) and/or Office of the Secretary of Defense (OSD). The Project Agreement Holder will be given the opportunity to become compliant with the guidance should they be found non-compliant. Failure to comply may result in termination.

The warranties and representations submitted as part of the proposal are hereby incorporated into this Project Agreement. The Project Agreement Holder was proposed as a nontraditional defense contractor and determined to be providing a significant contribution.

8. STATEMENT OF WORK

The Statement of Work, Attachment A, provides a detailed description of the work to be accomplished and reports and deliverables required by this Project Agreement. All changes to Attachment A must be incorporated via written modification to this Project Agreement. Additional guidance on report requirements is in Attachment B, Report Requirements.

9. TECHNICAL AND ADMINISTRATIVE REPRESENTATIVES

The following technical and contractual representatives of the Parties are hereby designated for this Project Agreement. Either party may change their designated representatives by written notification to the other.

MCDC CMF Contractual Representative:
Contracts Administrator
Advanced Technology International
315 Sigma Drive
Summerville, SC 29486
Email:
Phone:

Government Technical Representatives:
Agreements Officer Representative (AOR):

Email:
Phone:

Project Agreement Holder's Representatives:

Technical Representative:

777 Old Saw Mill River Rd
Tarrytown, NY 10591
Email:
Phone:

Contractual Representative:

777 Old Saw Mill River Rd
Tarrytown, NY 10591
Email:
Phone:

10. MARKING OF DELIVERABLES
Any Data delivered under this Project Agreement, by the Project Agreement Holder, shall be marked with a suitable notice or legend.

11. SECURITY ADMINISTRATION
The security level for this project is UNCLASSIFIED.

12. ATTACHMENTS
Attachments listed herein are hereby incorporated by reference into this Project Agreement.
A. Statement of Work, "Large-Scale Manufacturing of Antibodies Directed to SARS-CoV-2"
B. Report Requirements
C. Technical Direction Letter (TDL) RPP-20-08 Regeneron

13. GOVERNMENT FURNISHED PROPERTY
At this time, Government Furnished Property is not provided for use under this Project Agreement.

14. PATENT RIGHTS AND DATA RIGHTS
Please reference Section 7 of Attachment A, Statement of Work.

15. FOLLOW-ON PRODUCTION PROVISION
Please reference Section 1 of Attachment A, Statement of Work.

16. SECURITY & OPSEC
The below language shall be used as Paragraph 6 of Article XVII in Regeneron's Base Agreement: Access and General Protection/Security Policy and Procedures. This standard language text is applicable to ALL PAH employees working on critical program information or covered defense information related to Operation Warp Speed (OWS), and to those with an area of performance within an Army controlled installation, facility or area. PAH employees shall comply with applicable installation, facility and area commander installation/facility access and local security policies and procedures (provided by government representative). The PAH also shall provide all information required for background checks necessary to access critical program information or covered defense information related to OWS, and to meet installation access requirements to be accomplished by installation Provost Marshal Office, Director of Emergency Services or Security Office. The PAH workforce must comply with all personal identity verification requirements as directed by DOD, HQDA and/or local policy. In addition to the changes otherwise authorized by the changes clause of this agreement, should the Force Protection Condition (FPCON) at any individual facility or installation change, the Government may require changes in PAH security matters or processes.

17. ENTIRE AGREEMENT
This Project Agreement and the MCDC Base Agreement under which it is issued constitute the entire understanding and agreement between the parties with respect to the subject matter hereof.

Except as provided herein (including in the SOW), all Terms and Conditions of the MCDC Base Agreement and its modifications remain unchanged and in full force and effect.

Applied Technologies Center
315 Sigma Drive
Summerville, SC 29486
www.ati.org

The Project Agreement Holder is required to sign this document and return to Advanced Technology International to finalize this action.

Regeneron Pharmaceuticals, Inc.

By: /s/ Robert Landry

Name: Robert Landry

Title: Executive Vice President- Finance and Chief Financial Officer

Date: Jul 6, 2020

Advanced Technology International

By: /s/

Name: _____

Title: _____

Date: 6 July 2020

Attachment A
Statement of Work

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Statement of Work
For
Large-Scale Manufacturing of Antibodies Directed to SARS-CoV-2

RPP #: RPP-20-08
Project Identifier: MCDC OTA 2008-005, W15QKN-16-9-1002
Consortium Member: Regeneron Pharmaceuticals, Inc.
Title of Proposal: Large-Scale Manufacturing of Antibodies Directed to SARS-CoV-2

1.0 INTRODUCTION, SCOPE, AND OBJECTIVES

A. Preamble

Regeneron Pharmaceuticals, Inc. (referred to herein as “Regeneron”, “Offeror”, “Contractor” or “Recipient”) has demonstrated experience with rapid scale-up of biopharmaceutical programs. Our excellent history of receiving development scale processes from Research and Development (R&D) laboratories, and then expanding to clinical or commercial Good Manufacturing Practice (GMP) scale production, is well documented. Greater than 65 processes have been transferred since 2008 with a success rate of 100%. We have consistently demonstrated our ability to expedite the delivery of high quality, safe and efficacious products (Ebola therapeutic) in partnership with the Government (anti-MERS, anti-Ebola).
Fully human monoclonal antibodies (mAbs) are molecules with high potency, predictable Pharmacokinetics (PK), and limited off-target toxicity, and thus provide attractive types of therapeutics for emerging diseases. Importantly, we have repeatedly demonstrated that candidate mAb-based drugs to prevent and/or treat emerging infections, can be rapidly obtained from Regeneron’s proprietary VelocImmune® mice. Further, our ability to concurrently generate isogenic cell lines that are optimized for rapid antibody scale up and manufacturing using our proprietary Chemistry, Manufacturing, and Controls (CMC) platform technologies, have facilitated both testing of our mAbs in preclinical models and subsequent development of these mAbs into drugs suitable for human testing. In the process of completing many of these activities we have collaborated with other entities (including BARDA, Research Institutes, Government Laboratories and Universities). Our manufacturing has been designed to be paired with our proprietary VelocImmune® R&D technolo y, that i a proven proce to rapidly take a re earch concept from the bench, into large scale production, with the ability to delivery medicines to patients.

The Government has advised Regeneron that it is appropriate for the project described in this Project Agreement to be performed through the Medical CBRN Defense Consortium (MCDC), under the authority of the MCDC Other Transaction Agreement No. W15QKN-16-9-1002. Regeneron is amenable to performing the project pursuant to such authority, based on the advice of the Government, and due to the unprecedented circumstances of the Coronavirus Disease 2019 (COVID-19) pandemic and, accordingly, the parties have entered into this Project Agreement.

B. Overall Objectives and Scope

This project is defined by discrete work segments for the continuous manufacture of drug substance, formulated drug substance and filled, packaged and labeled drug product, in accordance with a mutually agreed schedule.

Pursuant to this project, Regeneron will manufacture and sell drug product to the applicable United States (U.S.) Federal Government agency, for distribution in the U.S. All manufacturing described herein will be compliant with Food and Drug Administration (FDA) current Good Manufacturing Oractices (cGMP), as 21 CFR 210 and 211.

1.1 Introduction

The objective is to conduct the manufacturing production activities described in this proposal for prototypes consisting of novel, proprietary mAb therapeutics and prophylactics, to reduce pathology of COVID-19 disease and/or prevent development of disease when administered prophylactically.

1.2 Scope

These manufacturing production activities will include manufacturing at-scale, filling and finishing, and storage and shipping of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)-specific monoclonal antibodies (referred to herein as the "prototype", the "prototype product", the "product" or "drug product") for treatment and/or prophylaxis against COVID-19.

1.3 Definition of the Prototype Project

Consistent with USG objectives, Regeneron will employ its proprietary manufacturing technology and processes, in a manner compliant with applicable laws and regulations, including 21 CFR 210 and 211 and the Drug Supply Chain Security Act, to manufacture the prototype product. This effort constitutes a prototype project because it will be used to evaluate the technical feasibility of manufacturing the prototype product during the ongoing COVID-19 pandemic. In addition, this is a prototype project because Regeneron will demonstrate, and prove-out the at-scale, multi-lot proprietary manufacturing activities of Regeneron in order to assess the feasibility of these activities to support the necessary quantity of the prototype product to treat the U.S. population. Successful completion of the prototype project will demonstrate Regeneron's capability to (i) rapidly manufacture product, which can be further scaled-up to meet mutually agreed to surge requirements with little advance notification and (ii) facilitate the Government's ability to stockpile and distribute large quantities of the drug product to respond when needed, including for use in clinical studies, under an Emergency Use Authorization (EUA), or pursuant to other clearance from the U.S. FDA. For clarity, any manufacturing and supply of drug product in excess of the specific quantities set forth in Section 4.0 of this Statement of Work, shall be subject to a separate mutual agreement between Regeneron and the Government.

The scope of effort supported by this agreement is further clarified in Section 1.4. It is important to note that nonclinical and clinical studies for the prototype are being conducted by Regeneron outside of this agreement. The results of those studies may be used to develop use case scenarios and, in turn, inform the USG's deployment strategy as it relates to product manufactured under this agreement; however, such results (including the degree to which the data are "positive" or "negative") shall not be a factor in this prototype project.

1.4 Objective

- Conduct its proprietary manufacturing production activities described in this proposal for prototypes consisting of novel, proprietary mAb therapeutics and prophylactics, to reduce pathology of COVID-19 disease and/or prevent development of disease when administered prophylactically.
- The prototypes will include one or more of the following, as mutually agreed between Offeror and the Government:
  - the mAbs known as REGN10987 and REGN10933, as a cocktail;
  - Other mAbs (as monotherapies or a cocktail) as agreed to by bilateral modification between Offeror and the Government.
- The deliverables will be the products listed above (i.e., REGN10987 and REGN10933), in the form of bulk formulated drug substance and/or filled and finished product in vials, as mutually agreed between Offeror and the Government, packaged and labeled drug product, results, reports and records associated with generation of data demonstrating quality and control.
- The products will be delivered in the form and quantity to be agreed between Offeror and the Government. It is expected that the prototypes will be stored by Offeror until such time as (a) they can be used for pre-clinical or clinical development purposes under an Investigational New Drug application (IND), or (b) upon the FDA's grant of an EUA under Section 564 of the Food, Drug and Cosmetic Act (FD&C Act), or full marketing approval under a full Biologics License Application (BLA) under Section 351(a) of the Public Health Service Act (PHSA).

1.5 Follow-on Activity

In accordance with 10.U.S.C. 2371b(f), and upon successful demonstration of the prototype, or at the accomplishment of particularly favorable or unexpected results achieved outside of this Agreement that would justify transitioning to production (e.g., EUA or BLA), additional at-scale manufacturing of up to 800,000 treatment courses, supported by a mutually agreed upon follow-on production contract or Other Transaction Agreement, may be awarded to Regeneron, without further competition, to partially or completely meet the USG objective of supplying a safe and effective COVID-19 therapeutic or prophylactic treatment courses to ensure nationwide access. For clarity, any manufacturing and supply of drug product in excess of the specific quantities set forth in Section 4.0 of this Statement of Work shall be subject to a mutually-agreed upon

separate agreement between Regeneron and the Government. For further clarity, neither party shall be obligated to negotiate or enter into such a separate agreement for follow-on production.

During the performance of the prototype project, the Government and contractor may negotiate the scope and price of follow-on production.

2.0 APPLICABLE REFERENCES

Current Good Manufacturing Practices, 21 CFR 210, 211

3.0 REQUIREMENTS

3.1 Technical

- The Offeror's technical approach is expected to be similar, but not duplicative, to its manufacturing activities under its current agreements with the Biomedical Advanced Research and Development Authority (BARDA), including contract # HHSO100201700016C, and will include the following:
    - Drug Substance, Formulated Drug Substance, Drug Product (DS/FDS/DP) quality and control.
        - Regeneron will apply statistical process analysis to continuously qualify in-process controls and release parameters.
        - The manufacturing process will be evaluated against parameters that are correlated to process performance and product quality. Ranges for the performance of each unit operation will be established through process development recommended ranges, the generation of statistical limits based on small-scale studies, and/or continuous commercial-scale manufacturing experience. These ranges will be monitored during the execution of quality and control, and are designed to ensure that the process is in a state of control and to ensure that the manufacturing process operates in a consistent and reproducible manner. The quality and control runs will also confirm that the process and product impurity profiles are within limits, demonstrate the consistent removal of impurities, and demonstrate that the process is capable of operating within acceptable microbiological control limits. Additional sampling and testing beyond that needed to assess process performance, may be completed to further process understanding.
        - *Intermediate Hold Time Validation*: Intermediate hold time validation to be performed via combination of at scale and small scale executions:
            - Microbial Control: Where appropriate, microbial control data from at scale hold time studies, will be leveraged from historical validation runs with molecules which have similar equipment and sanitization procedures.

- Chemical Stability: Chemical stability will be demonstrated using data from laboratory scale hold time studies performed for each of the prototypes, using material obtained from in-process pools from the 10,000 L manufacturing executions.

- *Media, Feed and Buffer Mixing Validation*: Preparation of buffers and media will be validated at commercial-scale. These validation studies will demonstrate that the preparation process consistently produces solutions meeting predefined limits for parameters indicative of homogeneity, such as pH, conductivity, osmolality, and turbidity. Where vessels of equivalent design and construction exist within the manufacturing facility, validation of media and buffer preparation will be performed on one representative vessel on at least three consecutive and successful executions.
- *Medium Storage Validation*: Medium storage validation will be separated into preparation hold and post-filtration storage, and has two components: microbial control and chemical stability. Pre-filtration microbial control is specific to the raw materials and the environment, and post-filtration microbial control is specific to each storage container and the ability of the storage container to maintain a microbial free condition. Maximum storage times for medium solutions with respect to microbial control will be validated as necessary at commercial scale, through preparation and storage of medium for extended storage times pre- and post-filtration. Validation will be achieved by demonstrating microbial control for a number of consecutive attempts established in the relevant validation protocol. Solutions will be prepared, stored for defined periods and tested for bioburden and endotoxin. Chemical stability of medium may be performed at small-scale to demonstrate storage conditions maintain integrity of chemical components. Bracketing approaches may be used to cover the different feeds and medium used, provided the individual protocol justifies the bracket.
- *Buffer Storage Validation*: Buffer storage validation is separated into preparation hold and post-filtration storage, and has two components: microbial control and chemical stability. Preparation holds are dependent on the solution composition. The worst- case solution for growth is determined using a risk-based approach, and post-filtration microbial control is specific to each vessel and the ability of a vessel to maintain a microbial free condition. Maximum storage times for buffer solutions will be validated as necessary at commercial-scale for microbial control, through preparation and storage of a non-growth inhibiting buffer for extended storage times pre- and post-filtration. Validation will be achieved by demonstrating microbial control for a number of consecutive attempts established by the protocol. Buffer hold validation in stainless steel vessels will require ongoing evaluation and monitoring; however, buffer hold validation in disposable bioprocess containers may be shortened, if appropriate, by a bracketing approach. Solutions will be prepared, held and monitored over time for bioburden, endotoxin. Chemical stability of buffers may be performed at small-scale to demonstrate that storage

conditions maintain integrity of chemical components. Bracketing approaches may be used to cover the large number of buffers used, provided the individual protocol justifies the bracket.

- *Chromatography Column Sanitization and Storage Validation*: Any newly required studies will be performed to validate the cleaning and storage procedures for [* * *] chromatography columns used in the manufacture of the prototypes. In addition, the maximum allowable storage period following cleaning will be established for each of the chromatography resins.
- *Chromatography Column Cleaning Validation*: The efficacy of the solutions used to clean the chromatography columns will be examined as necessary over three consecutive executions during commercial scale manufacturing of each of the prototypes. The effectiveness of the cleaning procedures will be assessed by sampling the post cleaning (post-use) Water for Injection (WFI) flush effluent; at approximately [* * *] into the flush for bioburden and endotoxin levels (the purpose of which is to demonstrate microbial control). In addition, Total Organic Carbon (TOC) will be measured to verify the absence of lot to lot protein carry over.
- *Chromatography Column Storage Validation*: The efficacy of the solutions used to store the chromatography columns will be examined, as necessary, over three consecutive executions during commercial scale manufacturing of each of the prototypes. The effectiveness of the cleaning and storage procedures will be assessed by sampling the post storage (pre-use) WFI flush effluent for bioburden, endotoxin levels and TOC. The maximum allowable storage period for each column will be established based on the shortest of the three consecutive executions for which the column remained in the storage solution.
- *Establishment of In-Process Control (IPC) Program*: The IPC program will utilize Statistical Process Control (SPC) to monitor critical and general process parameters, and critical and general quality attributes for each lot manufactured. On completion of quality and control activities, the IPC development report will establish the set of parameters and attributes to be monitored, and justify appropriate action limits for each. Upon approval of the development report, a Process Performance Monitoring (PPM) Plan will be generated containing the list of IPCs, historical data, selection of monitoring tools and response to signal strategy, statistical summary, and visualization of the IPCs. The IPC development report and PPM Plan will be further updated as laboratory and production scale characterization and validation data is gained, once defined production milestones are achieved, and then annually afterward. The annual updates will assess the overall state of process control and include process capability analysis and assessment of evidence of special cause variation for all applicable IPCs. Process data for individual lots will be monitored throu h [* * *] PPM meeting , where any trend i nal are identified and

responded to. These meetings will be attended by subject matter experts from departments including, but not limited to, [* * *]

- **Master Cell Bank (MCB) Genetic Characterization**: [* * *]
- **Working Cell Bank (WCB) Genetic Characterization**: [* * *]
- **DS/FDS/DP Registration Stability**: Stability studies for DS/FDS/DP will be initiated and executed according to stability protocols, International Council for Harmonisation (ICH) guidelines and internal procedures. Quality and control lots will be stored and monitored at the routine long term storage condition per the Specification for [* * *]. Samples will also be stored and monitored at Accelerated [* * *] condition for 6 months, and Stress [* * *] condition for [* * *] for the evaluation and identification of degradation pathways of the molecule. Stability studies performed on the quality and control lots will support the shelf life of each prototype, and confirm that the manufacturing process is suitable for commercial-scale manufacture. All testing will be conducted in a GMP Quality Control (QC) Laboratory. Any Out of Specification (OOS) or Out of Trend (OOT) results will be investigated.
- **DS/FDS/DP Shipping Validation**: Shipping Validation by actual transport will be performed on the DS/FDS/DP of each prototype to cover a distance and duration that will exceed routine shipment to the intended fill site. Successful shipping validation of intended shipping lanes is based on the ability of the container to maintain the product at a specified temperature, to preserve product quality, and meet specifications.
- **DS/FDS/DP Photostability Studies**: To determine overall photosensitivity of DS/FDS/DP per ICH requirements, a study will be performed at [* * *] under [* * *] and [* * *] light. Samples will be oriented for maximum light exposure using container closures designed for direct exposure, immediate pack/marketing pack, and a foil covered control. Testing will then be performed on [* * *] sample sets for stability indicating attributes.
- **QC Reference Standard Production and Stability**: Reference standards for the individual DS/FDS/DP GMP lots will be generated according to internal standard operating procedures. The DS/FDS/DP for each prototype will be filled as a product reference standard. The first manufactured lot (lead lot) will be sub-aliquoted into single use vials, stored and routinely monitored at [* * *] by Offeror's Quality Control personnel. The reference standard will be qualified prior to use, according to specifications. A Certificate of Qualification (CofQ) will be issued for each individual reference standard at the time of initial qualification and following recertification testing. A stability study to monitor the critical quality attributes of each reference standard will also be conducted.
- **Assay Validation**: Will be performed as necessary to support any applicable EUA or other regulatory requirements.
- **Manufacturing**: Following the completion of the activities described above, Offeror will manufacture prototypes at scale in order to achieve the intended scope of the contract.

- **Label/Pack**: Labeling and packaging of investigational product for clinical studies or for use under an EUA or approval, will be completed at a GMP contract manufacturing organization managed by Offeror's External Manufacturing group.
- **Storage**: Packaged and labeled material storage will be managed by Offeror's External Manufacturing group.

3.2 Management and Reporting

3.2.1 Program Management

Below are the individuals currently assigned to key roles on the project team. Regeneron reserves the right to make personnel changes which will be communicated accordingly.

a. Regeneron will manage, integrate and coordinate all activities, including utilizing Regeneron's state-of-the-art technical and administrative infrastructure to ensure efficient planning, initiation, implementation and direction of contracted activities.

b. The [* * *], is responsible for guiding the project approach and scope of this Program.

c. [* * *], will serve as Lead PI for this Program. The PI will be responsible for project management, communication, tracking, monitoring and reporting on status and progress, and modification to the project requirements and timelines, including any projects undertaken by subcontractors.

d. A [* * *], will be responsible for monitoring and tracking day-to-day progress and timelines, coordinating communication and project activities, costs incurred, and program management for this Program. The contract deliverables list identifies all contract deliverables and reporting requirements for this contract.

e. [* * *], will provide development of compliant subcontracts, consulting, and other legal agreements.

f. [* * *], will be responsible for financial management and reporting on all activities conducted by Regeneron and any subcontractors.

g. A [* * *], will be responsible for facilitating the development of integrated CMC plans and for monitoring and tracking the progress of the CMC milestones.

h. A [* * *], will be responsible for management of batch disposition, oversight of discrepancy investigations, and to ensure all released product conforms to GMP standards.

i. A [* * *], will be responsible for analytical method development, method transfer and specification development.

j. A [* * *], will be responsible for ensuring Regeneron quality, preclinical, and clinical drug development programs are conducted in compliance with regulations governing pharmaceutical drug development, and with project specific regulatory commitments/requirements ,and will serve as the liaison for communications with the US Food and Drug Administration.

k. Regeneron shall provide Quarterly Progress Reports, which shall include a description of the activities during the reporting period and the activities planned for the ensuing reporting period.

l. Regeneron shall provide Annual Progress Reports, which shall include a summation of the activities during the reporting period, and the activities planned for the ensuing reporting period.

m. Regeneron shall provide Draft and Final Reports, which shall include a summation of the work performed and results obtained for execution of various studies or technical work packages during the entire contract period of performance. This report shall describe the results achieved.

n. Regeneron shall participate in regular meetings to coordinate and oversee the contract effort, as directed by a single point of contact established by the Government. Such meetings may include, but are not limited to, meetings of Regeneron and subcontractors to discuss clinical manufacturing progress, product development, scale-up manufacturing development, preclinical/clinical study designs and regulatory issues, meetings with individual contractors and other Health and Human Services (HHS) officials to discuss the technical, regulatory, and ethical aspects of the program, and meetings with technical consultants to discuss technical data provided by Regeneron. Regeneron shall also consult with the Government as required in connection with meetings and submissions to regulatory agencies, including the FDA. The Government will establish a single point of contact for regular meetings and coordinate all requests for information through such point of contact, such that Regeneron shall not be required to attend multiple meetings with different Government agencies for the same (or similar) subject matter, or respond to multiple requests for information or materials concerning the same (or similar) subject matter.

o. Regeneron shall participate in teleconferences at an agreed upon frequency between Regeneron and -to review technical progress.

3.2.2 Integrated Master Schedule (IMS)

Regeneron will provide an Integrated Master Schedule within [* * *] of the award, and shall update such schedule to reflect any material changes. Within an agreed upon timeframe of the effective date of the contract, Regeneron will make any agreed upon changes between Regeneron and Agreements Officer and/or Project Officer at the the Government. The IMS shall be incorporated into the contract and will be used to monitor performance of the contract. Regeneron shall include the key milestones and Go/No-Go decision gates. The IMS for the period of performance will be accepted by the Government [* * *] of the Government's receipt of such IMS.

3.2.3 Reporting

On completion of a stage of the product development, as defined in the agreed upon IMS and Integrated Master Plan, Regeneron shall prepare and submit to the Project Officer and the Agreements Officer, reports from time to time that contain (i) reasonable detail, documentation and analysis to support successful completion of the stage according to the predetermined qualitative and quantitative criteria, and (ii) a description of the next stage of product development to be initiated, and a request for approval to proceed to the next stage of product development.

3.2.4 Data Management

Regeneron will utilize existing systems to implement data management and quality control systems/procedures, including transmission, storage, confidentiality, and retrieval of contract data. Provide analysis of data generated with contract funding to the Project Officer or Agreements Officer, upon request.

3.2.5 Technical and Financial Reporting

Technical Reports are described in Section 3.3.1 k., 1. and m. They are also listed in the milestone schedule and deliverables table in Section 5 of this Statement of Work.

For Financial Reporting, firm fixed price invoices will be submitted on a quarterly basis as described in Section 5 below. Invoices will include data and technical reports sufficient to support the accomplishment of each milestone, as appropriate, during the invoicing period. Regeneron will provide quarterly Financial Status Reports outlining billed vs. budgeted activity for each period, and in aggregate for the contract.

4.0 DELIVERABLES

Offeror assumed [* * *]; Filled/Finished Drug Product Deliveries [* * *]. Regeneron shall have the right to provide deliverables directly to the Government and not to the Consortium Management Firm (CMF).

Deliverable Table (June 2020 - June 2021)

Deliverable	Due Date	Total Program Funds	Data Rights
Project Kick-Off; Deliverable	[* * *]	[* * *]	*Specially Negotiated
DS/FDS Bulk GMP Lot [* * *]	[* * *]	[* * *]	*Specially Negotiated
DS/FDS Bulk GMP Lot [* * *]	[* * *]	[* * *]	*Specially Negotiated
DS/FDS Bulk GMP Lot [* * *]	[* * *]	[* * *]	*Specially Negotiated
Fill Product [* * *]	[* * *]	[* * *]	*Specially Negotiated
Fill Product [* * *]	[* * *]	[* * *]	*Specially Negotiated
Fill Product [* * *]	[* * *]	[* * *]	*Specially Negotiated
Package/Label Product	[* * *]	[* * *]	*Specially Negotiated
Storage of Drug Product in VMI [* * *]	[* * *]	[* * *]	*Specially Negotiated
Storage of Drug Product in VMI [* * *]	[* * *]	[* * *]	*Specially Negotiated
Storage of Drug Product in VMI [* * *]	[* * *]	[* * *]	*Specially Negotiated
Storage of Drug Product in VMI [* * *]	[* * *]	[* * *]	*Specially Negotiated
Quarterly Technical and Business Status Report, see above for submission schedule	[* * *]	[* * *]	*Specially Negotiated
Annual Technical and Business Status Report, see above for submission schedule	[* * *]	[* * *]	*Specially Negotiated
Quarterly Technical and Business Status Report, see above for submission schedule	[* * *]	[* * *]	*Specially Negotiated
[* * *]	[* * *]	[* * *]	Limited Rights
		$450,262,000 (FFP)	

*Upon payment, delivery and acceptance in accordance with the terms of this Project Agreement, the Government will have title to the product produced under this Statement of Work. The Government will have the rights described below in Section 7.3 to technical data disclosed under this Statement of Work.
** Packaging and labeling of product will be performed following the determination of the use of the applicable drug product (e.g., for clinical trials or for distribution under an EUA or BLA).

5.0 MILESTONE PAYMENT SCHEDULE; TERMINATION COSTS

Milestone #	Milestone Description (Deliverable Reference)	Due Date	Total Program Funds
5.1	[* * *] Drug Substance Deliverables [* * *] of Drug Substance)	[* * *]	[* * *]
5.2	[* * *] Drug Substance Deliverables [* * *] of Drug Substance)	[* * *]	[* * *]
5.3	[* * *] Drug Substance Deliverables (Fill/Finish for [* * *] of Drug Substance)	[* * *]	[* * *]
5.4	[* * *] Drug Substance Deliverables [* * *] of Drug Substance)	[* * *]	[* * *]
5.5	[* * *] Drug Substance Deliverables (Fill/Finish for [* * *] of Drug Substance)	[* * *]	[* * *]
5.6	Quarterly Technical and Business Status Report, Reference 3.3.1.k	[* * *]	[* * *]
5.7	Annual Technical and Business Status Report; Reference 3-3.1.1	[* * *]	[* * *]
5.8	Storage of Drug Product in VMI [* * *]	[* * *]	[* * *]
5.9	Storage of Drug Product in VMI [* * *]	[* * *]	[* * *]
5.10	Storage of Drug Product in VMI [* * *]	[* * *]	[* * *]
5.11	Storage of Drug Product in VMI [* * *]	[* * *]	[* * *]
		Total (Include Payment Type; FFP):	**$450,262,000**
		Period of Performance:	**June 2020 – June 2021**

The overall price is fixed price at $450,262,000. Milestone payments will be made quarterly as set forth in the table above, corresponding to the deliverables and any 3rd party commitments Regeneron needs to make. In the event the deliverables in a given quarter are less than or exceed the projected quantity, the milestone payment for such quarter will be equitably adjusted based on the shortfall or excess amount, as applicable, however the price will not exceed $450,262,000 Milestone payment terms will be net 30 days.

Total pricing is a firm fixed price per lot, [* * *]. Regeneron will deliver [* * *] of filled/finished drug product. Regeneron will be entitled to full payment for drug product upon delivery/

acceptance (as described herein) of filled/finished drug product, prior to packaging and labeling. However, Regeneron shall be responsible for the packaging and labeling of product at no additional cost following the determination of the use of such drug product (e.g., for clinical trials or for distribution under an EUA or BLA). Drug product will comply with the Drug Supply Chain Security Act serialization and tracking requirements. Drug product will not be co-formulated, except as otherwise mutually agreed by the parties. Unless and until otherwise mutually agreed, the drug product produced under this Statement of Work will be filled for therapeutic use. In order to change this allocation, Regeneron will require at least [* * *] prior written notice, in order to meet Regeneron's notification requirements to its fill/finish subcontractor. Regeneron will provide the Government with the timeline for fill/finish activities, including the dates by which the parties must determine the allocation of fill/finish activities. Notwithstanding the foregoing, as part of this Project Agreement, Regeneron will have the right to utilize material and capacity supported by this agreement to fill up to [* * *], as well as any additional drug product mutually agreed upon by Regeneron and the Government (with respect to which use the Government will not unreasonably withhold consent.

In the event this Statement of Work is terminated prior to completion, termination costs recoverable by Regeneron under Section 2.04 of the MCDC Base Agreement, shall include the following: the full contract price for any drug product manufactured and not yet paid for; a pro-rated portion of the contract price for drug substance or drug product that is in process, based on the stage of production, [* * *], and raw materials that Regeneron purchased (or is obligated to purchase) that cannot be allocated to other products.

6.0 STORAGE AND SHIPPING PROVISIONS

Upon acceptance by the Agreements Officer Representative of any lot of antibodies under this contract, title to such antibodies will transfer as follows: upon delivery of drug product to vendor-managed inventory and the Government's corresponding written acceptance of the delivery of each such lot of drug product. The Government shall accept product that conforms to contract requirements based on a Certificate of Analysis (COA) provided by Regeneron. The Government's acceptance of product will be [* * *] provide written notice of acceptance or rejection [* * *]. Unless otherwise mutually agreed upon by the parties, drug product shall be shipped to the Government within the continental United States. Regeneron will [* * *] for all product stored as vendor-managed inventory. To the extent that Regeneron is responsible for the correction, repair or replacement of Government property held in vendor-managed inventory [* * *] the Government will [* * *] of such property. Vendor-managed storage of product manufactured under this agreement is supported through June 30, 2021 and, as such, the Government must either (a) take possession on or before this date and provide Regeneron with disposition instructions in sufficient time to transfer physical material from Regeneron by this date or (b) bilaterally modify this agreement to extend the period of vendor management of storage prior to this date.

The Government understands that prices identified in this contract include [* * *] applicable to material that will become Government property, including product stored as vendor-managed inventory.

7.0 PATENT RIGHTS; DATA RIGHTS; PREP ACT AND TRANSPARENCY

Article X, ("PATENT RIGHTS") and Article XI. ("DATA RIGHTS") of Other Transaction Agreement number W15QKN-16-9-1002 shall not apply to this Project Agreement and are hereby replaced for the purpose of this Project Agreement, with this Section 7.0 (including Sections 7.1-7.4 and the Definitions Appendix).
Definitions:

Capitalized term u ed in thi Section 7 0 (including Section 7 1 7 4) hall have the meanin a cribed to uch term in the Definitions Appendix to this Project Agreement.

For purposes of this Project Agreement, all rights of the Government in and to Data or Subject Inventions are granted solely to The United States of America, as represented by the Department of Health & Human Services, Office of the Assistant Secretary for Preparedness & Response ("ASPR"), Office of Biomedical Advanced Research and Development ("BARDA") (represented by Office of Acquisition Management, Contracts and Grants (AMCG)) and to no other agency of the United States of America (including JPEO) or representative of any such other agency (including the CMF). The parties acknowledge that Regeneron is permitted to communicate solely with BARDA regarding the matters described in this Section 7.0 (including Sections 7.1-7.4) and is not obligated to communicate with any other Government agency or representative regarding such matters.

7.1 BACKGROUND INTELLECTUAL PROPERTY

Each party acknowledges that it has no rights to the other party's inventions, discoveries, know-how, Data, technology or intellectual property generated, discovered, conceived or reduced to practice prior to or otherwise outside of this Statement of Work (also referred to herein as, this "Project Agreement" or this "Agreement"), and any improvements or modifications thereto, including, without limitation, the background intellectual property (and improvements/modifications) for the Government and Re eneron de cribed below, a follow

Government Background Intellectual Property. None.

Contractor Background Intellectual Property: Includes, but is not limited to, [* * *]:

63/004,312, filed April 2, 2020 "Anti-SARS-CoV-2-Spike Glycoprotein Antibodies and Antigen-Binding Fragments"

[* * *]

63/014,687, filed April 23, 2020 "Anti-SARS-CoV-2-Spike Glycoprotein Antibodies and Antigen-Binding Fragments"

[* * *]

63/025,949, filed May 15, 2020 "Anti-SARS-CoV-2-Spike Glycoprotein Antibodies and Antigen-Binding Fragments"

[* * *]

[* * *]

63/034,865, filed June 4, 2020 “Anti-SARS-CoV-2-Spike Glycoprotein Antibodies and Antigen-Binding Fragments”

[* * *]

[* * *]

[* * *]

[* * *]

[* * *]

[* * *]

[* * *]

[* * *]

No party relinquishes rights in any of its background intellectual property to any other party under this contract.

Either Party may update its disclosure of background intellectual property under this Section 7.1 upon written notice to the other Party.

7.2 PATENT RIGHTS

a. Allocation of Principal Rights

The parties agree that the Bayh-Dole statute does not apply to this Project Agreement. Ownership of inventions Made in the performance of this Project Agreement shall follow inventorship, and inventorship shall be determined in accordance with United States patent laws. With respect to any Subject Invention Made (in whole or in part) by or on behalf of Regeneron, unless Regeneron shall have notified the Government (in accordance with Subparagraph b. below) that Regeneron does not intend to properly disclose and elect title to a Subject Invention, Regeneron shall retain the entire right, title, and interest throughout the world to such Subject Invention, and the Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the Subject Invention throughout the world. This license does not include the right to use or allow others to use the Subject Invention for commercial purposes. If Regeneron does not properly disclose and elect title to any such Subject Invention (in accordance with Subparagraph b. below), then the Government may exercise its rights to seek ownership of such Subject Invention, pursuant to clause 7.2.c. below.

b. Invention Disclosure, Election of Title, and Filing of Patent Application

i. Regeneron shall disclose in writing each Subject Invention to the OTTR within 12 months after the inventor discloses it in writing to Regeneron personnel responsible for patent matters. The disclosure shall identify the inventor(s) and this Project Agreement under which the Subject Invention was made. It shall be sufficiently complete in technical detail to convey a clear understanding of the Subject Invention. The disclosure shall also identify any publication, on sale (i.e., sale or offer for sale), or public use of the Subject Invention, or whether a manuscript describing the Subject Invention has been submitted for publication and, if so, whether it has been accepted for publication. In addition, after disclosure to the Government funding agency (HHS/BARDA), Regeneron shall promptly notify the OTTR of the acceptance of any manuscript describing the Subject Invention for publication and any on sale or public use.

ii. Regeneron shall elect in writing whether or not to retain ownership of any Subject Invention by notifying the OTTR within 2 years of disclosure to the Government funding agency. However, in any case where publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, the period for election of title may be shortened by the agency to a date that is no more than 60 calendar days prior to the end of the statutory period.

iii. Regeneron shall file either a provisional or a non-provisional patent application for an elected Subject Invention within 1 year after election of title. However, in any case where a publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, Regeneron shall file the application prior to the end of that statutory period. If Regeneron files an initial provisional application, it shall file a non-provisional application within 10 months of the filing of the initial provisional application. Regeneron shall include a Government Support Clause (GSC) within the specification of any United States patent applications and any patent issuing thereon covering a subject invention.

iv. Regeneron may request extensions of time for disclosure, election, or filing under subparagraphs (b)(i), (b)(ii) and (b)(iii) of this clause. An extension of time for each deadline, may be granted at the discretion of the Government funding agency.

v. If Regeneron determines that it does not intend to elect to retain title to any such Subject Invention, Regeneron shall notify the Government, in writing, within two (2) years of disclosure to the Government. However, in any case where publication, sale, or public use has initiated the one (1)-year statutory period wherein valid patent protection can still be obtained in the United States, the period for such notice may be shortened by the Government to a date that is no more than sixty (60) calendar days prior to the end of the statutory period.

c. Conditions When the Government May Obtain Title

Upon the Government's written request, Regeneron shall convey title to any Subject Invention to the Government funding agency if Regeneron fails to disclose the Subject Invention or elects not to retain title to the Subject Invention within the times specified in Subparagraph b of Section 7.2. The Government may request title after learning of the failure of Regeneron to disclose or elect within the specified times for an unlimited time. The Government funding agency may request title upon Regeneron's omission to timely file patent applications in any country. The Government funding agency may request title in any country in which Regeneron decides to discontinue prosecution.

d. Rights to Regeneron and Protection of Regeneron's Right to File

Regeneron shall retain a fully paid up, sub-licensable, nonexclusive, royalty-free license throughout the world in each Subject Invention to which the Government obtains title. Regeneron license extends to Regeneron's subsidiaries and other affiliates (outside this Agreement), if any, within the corporate structure of which Regeneron is a party and includes the right to grant licenses of the same scope to the extent that Regeneron was legally obligated or permitted to do so at the time the Project Agreement was executed. The license is otherwise transferable only with the approval of the Government, except when transferred to an Affiliate or successor of that part of Regeneron's business to which the Subject Invention pertains. The Government approval for license transfer shall be provided on a timely basis (and in no event later than 90 calendar days following Regeneron's request) and shall not be unreasonably withheld.

i. The Regeneron license may be revoked or modified by the Government to the extent necessary to achieve expeditious Practical Application of the Subject Invention pursuant to an application for an exclusive or nonexclusive license submitted consistent with appropriate provisions at 37 CFR Part 404. Regeneron's license shall not be revoked in that field of use or the geographical areas in which Regeneron has achieved Practical Application of the Subject Invention and continues to make the benefits of the Subject Invention accessible to the public.

ii. Before revocation or modification of Regeneron's license, the Government shall furnish Regeneron with a written notice of its intention to revoke or modify the license, which notice shall include a detailed explanation of the reasons for such revocation or modification, and Regeneron shall be allowed thirty (30) calendar days (or such other time as may be authorized for good cause shown) after the notice to show cause why the license should not be revoked or modified.

e. Action to Protect the Government's Interest

Regeneron agrees to execute or to have executed and promptly deliver to the Government all instruments necessary to (i) establish or confirm the rights the Government has throughout the world in those Subject Inventions to which Regeneron elects to retain title, and (ii) convey title to

the Government when requested under Subparagraph c of this Section 7.2 and to enable the Government to obtain patent protection throughout the world in that Subject Invention.

i. Regeneron agrees to require, by written agreement, its employees, other than clerical and non-technical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by Regeneron, each Subject Invention made under this Agreement so Regeneron can comply with the disclosure provisions of this Section 7.2. Regeneron shall use reasonable efforts to instruct employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

ii. Regeneron shall notify the Government of any decisions not to continue the prosecution of a patent application for a Subject Invention, pay maintenance fees, or defend in a reexamination or opposition proceedings on a patent of a Subject Invention, in any country, not less than thirty (30) calendar days before the expiration of the response period required by the relevant patent office.

Regeneron shall include, within the specification of any United States patent application and any patent issuing thereon covering a Subject Invention, the following statement: “This invention was made with Government support under Agreement **MCDC2020-504**, awarded by the U.S. Department of Health and Human Services. The Government has certain rights in the invention.”

f. Lower Tier Agreements

Regeneron shall ensure that its Affiliate agreements and Sub-Recipient Agreements regardless of tier, for experimental, developmental, or research work entered into after the Effective Date and submitted for reimbursement under this Agreement, contain invention reporting and assignment requirements sufficient to permit Regeneron to comply with this Section 7.2.

g. Reporting on Utilization of Subject Inventions

i. Regeneron agrees to submit, during the term of this Project Agreement, an annual report on the utilization of a Subject Invention or on efforts at obtaining such utilization that is being made by Regeneron or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commercial sale or use, and such other data and information as the agency may reasonably specify. Regeneron also agrees to provide additional reports as may be requested by the Government in connection with any march-in proceedings undertaken by the Government in accordance with Subparagraph h of this Section 7.2. Consistent with 35 U.S.C. § 202(c)(5), the Government agrees it shall not disclose such

information to persons outside the Government without permission of Regeneron.

ii. All required reports shall be submitted to the e-room, OTAS, OTAO, and OTTR.

h. Compulsory Licensing Rights

Regeneron agrees that, with respect to any Subject Invention in which it has retained title, the Government has the right to require Regeneron, an assignee, or exclusive licensee of a Subject Invention to grant a non-exclusive license to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if Regeneron, assignee, or exclusive licensee refuses such a request, the Government has the right to grant such a license within the Field itself *only* if the Government determines that:

i. Action is necessary to alleviate the following health or safety needs that may affect the United States and Regeneron (itself or through its assignee, subcontractor or licensee) is unwilling or unable to manufacture or supply the Subject Invention to address such needs:
   a. Declaration for Public Health Emergency by the Secretary of HHS;
   b. Determination that there is a significant potential for a public Health emergency that has a significant potential to affect a national or health security of U.S. citizens as determined by the Secretary of HHS; or
   c. Declaration by WHO Director General of a public health emergency of international concern.

7.3 DATA RIGHTS

a. Allocation of Principal Rights

i. For Data produced under this SOW including Computer Software, to the extent developed with Government funds provided under this SOW, except as expressly provided elsewhere in this Project Agreement (including Section 7.3.b.), Regeneron grants to the Government a paid-up, nonexclusive, nontransferable, irrevocable, worldwide license in such Data (a) to exercise Government Purpose Rights for a period of ten (10) years following the production of such Data, (b) to exercise Unlimited Rights followin the expiration of uch ten (10) year period For Data produced under thi Project A reement, excluding Computer Software, to the extent developed with private funds and for other Data designated by Regeneron as “Limited Rights Data”, Regeneron grants to the Government a paid-up, nonexclusive, nontransferable, irrevocable, worldwide license in such Data to exercise Limited Rights. The Government will not obtain any rights in Computer Software produced

under this Project Agreement to the extent developed with private funds. For certificates of analysis and batch records pertaining to drug product purchased under this Project Agreement, the Government shall have Unlimited Rights.

ii. Regeneron agrees to retain and maintain in good condition all Data produced under this Project Agreement and necessary to achieve Practical Application of any Subject Invention in accordance with Regeneron's established record retention practices. In the event of an exercise of the Government's compulsory licensing rights as set forth under Section 7.2.h., Regeneron agrees, upon written request from the Government, to deliver at no additional cost to the Government, all existing Data produced under this Project Agreement necessary to achieve Practical Application of the relevant Subject Invention within sixty (60) calendar days from the date of the written request.

iii. Regeneron's right to use Data is not restricted and includes the right under Regeneron's established business policies to make public research Data (especially human research Data) by publication in the scientific literature, by making trial protocols, trial results summaries, and clinical studies reports publicly available, and by making trial patient-level data available for third-party analysis.

b. Proprietary Manufacturing Data

Notwithstanding anything to the contrary in this Project Agreement, Regeneron retains all rights in and to Data relating to or comprising Regeneron's proprietary manufacturing technology and processes, including any trade secrets, Chemistry, Manufacturing and Controls information (CMC Data), and Data concerning or arising from test method development, device or delivery system development, assay development, formulation, quality assurance/quality control development, technology transfer, process development and scale-up and cell-line development, and the Government shall have no rights to use such Data independently from this Agreement or to disclose such Data to any third party. Regeneron may designate certain Data concerning its manufacturing activities as Limited Rights Data, in which case the Government shall have Limited Rights in and to such Data. Regeneron will use reasonable efforts to mark any Limited Rights Data delivered under this Project Agreement with appropriate Limited Rights markings.

c. Identification and Disposition of Data

Regeneron shall keep copies of all Data relevant to this Project Agreement as required by the Food and Drug Administration (FDA) for the time specified by the FDA. The Government reserves the right to review any other data determined by the Government to be relevant to this Agreement. The Government further acknowledges that Regeneron holds the commercialization rights for all products developed under this Agreement in the U.S. and will be responsible for their registration with the FDA. This provision is subject to any applicable limitations on the Government's rights under Article VIII.B.a-b of the BARDA OTA.

7.4 REGULATORY RIGHTS

The Contractor agrees to the following:

a. Regulatory Data. Regeneron shall provide to the OTTR and OTAS copies of formal FDA submissions pertaining to the scope of the project, no later than 10 business days before submission to the FDA. For clarity, CMC Data included in such submissions shall be subject to Section 7.3.b.

b. Rights of Reference. Upon mutual agreement, Regeneron will grant to the Government a right of reference to any Regulatory Application submitted in support of this Project Agreement, solely for the purpose of the Government conducting a clinical trial with the drug product supplied under this Project Agreement under a protocol approved by Regeneron for performance by the Government. In such a case, Regeneron agrees to provide a letter of cross-reference to the Government and file such letter with the appropriate FDA office. Nothing in this paragraph reduces the Government's data rights as articulated in other provisions of this award.

c. Clause 7.4.b. will survive the acquisition or merger of the Contractor by or with a third party. This clause will survive the expiration of this contract.

7.5 PREP Act Coverage. It is the intent of the Parties that the drug product provided pursuant to this Agreement be covered by the March 10, 2020 declaration under the Public Readiness and Emergency Preparedness Act (PREP Act), 42 U.S.C. § 247d-6d, 85 Fed Reg. 15,198 (March 17, 2020), or any amendments thereto that provides liability protection for such use. Based on an independent review by each of the Parties of the PREP Act Declaration issued by DHHS on March 10, 2020, pursuant to section 319F-3 of the Public Health Service Act (42 U.S.C. 247d-6d), and a related advisory opinion issued by the DHHS Office of General Counsel on April 14, 2020, the Parties believe that Regeneron is a covered person eligible for immunity under the PREP Act for activitie related to medical countermea ure again t COVID 19 To the extent DoD or BARDA i authorized to do o a an Authority Having Jurisdiction, the Government designates Regeneron as a covered person eligible for immunity under the PREP Act Declaration issued by DHHS on March 10, 2020, pursuant to section 319F-3 of the Public Health Service Act (42 U.S.C. 247d-6d), for activities related to medical countermeasures against COVID-19. The Government further warrants that the drug product provided pursuant to this Project Agreement will not be (a) sold to any entity nor will it be returned after acceptance under the terms of this contract or (b) distributed or used, or authorized for distribution or use, outside the United States or to the extent such activities are not protected from liability under an active PREP Act declaration.

7.6 Transparency. To the extent permitted under applicable laws, the Government will provide Regeneron in a timely manner copies of reports concerning this Project Agreement that are provided to other Government agencies or legislative or executive branches of the government.

8.0 SECURITY

The security classification level for this effort is UNCLASSIFIED.

9.0 MISCELLANEOUS REQUIREMENTS (SAFETY, ENVIRONMENTAL, ETC.)

N/A

10.0 GOVERNMENT FURNISHED PROPERTY/MATERIAL/INFORMATION

None

11.0 AGREEMENTS OFFICER'S REPRESENTATIVE (AOR) AND ALTERNATE AOR CONTACT INFORMATION

AOR

NAME:
EMAIL:
PHONE:
AGENCY NAME/DIVISION/SECTION: HHS/ASPR/BARDA

Alternate AOR

NAME:
MAILING ADDRESS:
EMAIL:
PHONE:
AGENCY NAME/DIVISION/SECTION:

Requiring Activity:
US Department of Health & Human Services (HHS), Assistant Secretary for Preparedness and Response (ASPR), Biomedical Advanced Research and Development Authority (BARDA)

Computer Software:

To perform and further this Project Agreement:

Computer programs that comprise a series of instructions, rules, routines, or statements, regardless of the media in which recorded, that allow or cause a computer to perform a specific operation or series of operations; and

Recorded information comprising source code listings, design details, algorithms, processes, flow charts, formulas, and related material that would enable the computer program to be produced, created, or compiled.

Does not include computer databases or computer software documentation.

Data: Means recorded information, regardless of form or the media on which it may be recorded. The term includes technical data and Computer Software. The term does not include information incidental to contract administration, such as financial, administrative, cost or pricing, or management information.

Field: The development of anti-pathogen assets to treat, diagnose or prevent emerging infectious diseases.

Government: The United States of America, as represented by the Department of Health & Human Services ("Government"), Office of the Assistant Secretary for Preparedness & Response ("ASPR"), Office of Biomedical Advanced Research and Development ("BARDA") (represented by Office of Acquisition Management, Contracts and Grants (AMCG)).

Government Purpose: Any activity in which the United States Government is a party, including cooperative agreements with international or multi-national defense organizations, or sales or transfers by the United States Government to foreign governments or international organizations. Government purposes include competitive procurement, but do not include the rights to use, modify, reproduce, release, perform, display, or disclose technical data for commercial purposes or authorize others to do so.

Government Purpose Rights: The rights by Government to—

1. Use, modify, reproduce, release, perform, display, or disclose technical data within the Government without restriction; and

2. Release or disclose technical data outside the Government and authorize persons to whom release or disclosure has been made to use, modify, reproduce, release, perform, display, or disclose that data for United States Government Purpose.

Invention: Any invention or discovery that is or may be patentable or otherwise protectable under Title 35 of the United States Code.

Limited Rights: The rights to use, modify, reproduce, perform, display, or disclose Data, in whole or in part, within the Government solely for research purposes for the Field. Government will ensure that disclosed information is safeguarded in accordance with the restrictions of this Agreement. The Government may not, without the prior written permission of Recipient, release or disclose the Data outside the Government, use the Data for competitive procurement or manufacture, release or disclose the data for commercial purposes, or authorize the Data to be used by another party. The Parties shall maintain the confidentiality of all Data subject to or designated as falling within Limited Rights.

Limited Rights Data: Data, other than Computer Software, that embody trade secrets or are commercial or financial and confidential or privile ed, to the extent that uch Data pertain to item , component , or proce e developed at private expen e, including minor modifications.

Made: The conception or first actual reduction to practice of the invention as defined in this Agreement.

Option: An option, entered into by bilateral agreement pursuant to a Statement of Work and budget, by which, for a specified time, the Government may elect to purchase additional supplies or services called for by the Agreement.

Other Transaction Agreement Officer ("OTAO"): Is the responsible Government official authorized to bind the Government by signing this Agreement and bilateral modifications.

Other Transaction Agreement Specialist ("OTAS"): Is a supporting official that assists and represents the OTAO. The OTAO is the only official who can bind the Government.

Other Transaction Agreement Technical Representative ("OTTR"): Is the primary Government official for all technical matters on the Agreement.

Practical Application: With respect to a Subject Invention, to manufacture, in the case of a composition or product; to practice, in the case of a process or method; or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the Subject Invention is capable of being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public for a regulatory approved product.

Subject Invention: Any Invention Made in the performance of work under this Agreement within the Field for which Recipient pursues a patent.

Sub-Recipient: Akin to a subcontractor. Any supplier, distributor, vendor, or firm that furnishes supplies or services to or for the Recipient, an Affiliate, or a Sub-Recipient. A Sub-Recipient differs from an Affiliate in that Sub-Recipients are not listed as an Affiliate in Attachment 3 and may be used to execute tasks under the SOW by Recipient or Affiliate.

Sub-Recipient Agreement: Any contract entered into by a Sub-Recipient to furnish supplies or services for performance of this Agreement. This term describes an agreement with a 1st-Tier Sub-Recipient, except as expressly noted in this Agreement.

Attachment B
Report Requirements

This page intentionally left blank. See separate document for Attachment B.

REPORT REQUIREMENTS

If classified information is required to be submitted under this Agreement, it must be submitted to the addresses specified in the SOW or DD254. No classified information should be submitted directly to ATI.

Any applicable Contract Data Requirements Lists (CDRLs), Data Item Descriptions (DIDs) or other report guidance for this Project may be included at the end of this attachment.

ATI, in addition to the AOR, must receive a copy of the Quarterly Status Reports and the Final Status Report. Quarterly Status Reports, Annual Status Reports, and Final Status Reports should be submitted to . All other deliverables shall be submitted to the AOR only, but ATI must be notified that the deliverable has been submitted to the AOR. The AOR will provide ATI a completed Sign- off Memorandum as evidence the milestone deliverable was received and deemed acceptable.

If you would like a copy of the Report Requirements template in MS Word, please email

A. QUARTERLY STATUS REPORT

The Recipient shall submit or otherwise provide a Quarterly Status Report in the format as shown in this attachment on the last day of the month of the calendar quarter (i.e., **March 31, June 30, and December 31**). A sample template is provided.

I. The Recipient's Technical Status Report will, at a minimum, address the following: Comments on Technical/Cost/Schedule Performance, Project Quad Chart, Milestone Status, Non-Traditional Defense Contractor Participation and Plans for the Next Quarter.

B. PAYABLE MILESTONES/DELIVERABLES

The Recipient shall submit to the Agreements Officer Representative and MCDC CMF Representative documentation describing the extent of accomplishment of Payable Milestones and Deliverables.

I. **Submission of Payable Milestones/Deliverables**. The Recipient is required to submit all deliverables identified as Payable Milestones, as shown in the Payable Milestone Schedule, as well as any other deliverables/reports listed in the Statement of Work.

II. **Sign-off Memorandum.** The Sign-off Memorandum as shown in this attachment shall accompany all submissions indicated in section B.I. The Agreements Officer Representative shall provide written approval using the Sign-off Memorandum to the MCDC Consortium Management Firm. The Sign-off Memorandum will be used to verify that all submissions are technically acceptable. It will also be used to substantiate invoice payment for firm fixed price agreements.

C. ANNUAL STATUS REPORTING

I. The Project Agreement Holder shall submit an Annual Status Report on **September 30** each year (same format as Quarterly Status Report for one year period) for all projects whose periods of performances are greater than

one year in accordance with the terms and conditions of the MCDC Base Agreement. The Annual Status Report must also include the following:

i. A comparison of actual accomplishments with the goals and objectives of the project established for the period.
ii. Reasons why established goals and objectives were not met, if appropriate.
iii. A cumulative chronological list of written publications in technical journals. Include those in press as well as manuscripts in preparation and planned for later submission. Indicate likely journals, authors and titles.
iv. Papers presented at meetings, conferences, seminars, etc.
v. New discoveries, inventions or patent disclosures and specific applications stemming from the individual project provided that such disclosure shall not compromise the rights of the inventor.
vi. Reporting on Utilization of Subject Inventions should be included in the Annual Status Report per Section 10.08 of the Base Agreement.

Quarterly Status Report

for

<Project Agreement Holder Name>

Project No. MCDC-XX-XX-XXX

Reporting Period: DATE - DATE

Project Agreement Holder

<Project Lead>

<Other Project Team Member(s)>

Project Team Technical POC

Name Company Street Address
City, State Zip Code Phone Number Email address

Submitted: ***<date>***

1. Comments on Technical/Cost/Schedule Performance

The purpose of this section is to bring project stakeholders up to speed on current project status. It is not intended to be a line-by-line account of the quarter's activities; details of that nature are reserved for the latter section of this report. Rather, this section should highlight technical, cost, and schedule performance for the quarter, and report overall progress towards successful technology transition and implementation – an executive summary-like synopsis. This section should also be used to cite project-related concerns.

Properly crafted, this section is typically about one-half page in length.

2. Project Quad Chart

Quad charts are used for many purposes, including high level briefings. Therefore, it is imperative that information be current and accurate, especially in regards to the lower quadrants. The text - where populated - in the quad chart below is for sample purposes only.

<table>
<tr><th colspan="2">< Project Agreement Title></th></tr>
<tr><td colspan="2"></td></tr>
<tr><th>Goals & Objectives</th><th>Project Information</th></tr>
<tr><td>Briefly describe the goals of the project; include the technical objectives and the implementation targets.</td><td>Project Lead:
Team Members:
Period of Performance:
Funding:
Cumulative Amt Invoiced:
Total Cost Share Reported:</td></tr>
<tr><th>Milestones & Technical Achievements</th><th>Implementation & Payoff</th></tr>
<tr><td>Apr 16: Kickoff Meeting
Jun 16: Design Analysis complete
Jul 16: Materials/Equipment Rec'd
Oct 16: Prototype construction complete
May 17: Initial testing complete
Oct 17: Production units implemented in shipyard processes</td><td>Schedule: Target date for implementation.
Status: Current status towards implementation event.

Briefly describe what benefits will accrue from this project's successful completion and implementation. Be quantitative to the greatest extent possible.</td></tr>
<tr><td colspan="2">Current Status: Technical = Green/Yellow/Red (delta) Schedule = Green/Yellow/Red (delta) Cost = Green/Yellow/Red (delta)</td></tr>
</table>

Current Status Legend: Green = Good/On Budget Yellow = Minor Weakness/Known Risk Red = Major Weakness/Critical Delta: = upgrade from last assessment; = downgrade from last assessment; = no change

3. Supplemental Information

In order to improve the usefulness of the quad charts and provide sufficient project information, the Quarterly Status Report must be supplemented with data described below.

3.1 Milestone Status:

No.	Milestone	Due Date	Percent Complete This Period	Cumulative Percent Complete
1				
2				
3				

3.2 Non-Traditional Defense Contractor Participation

Name of Nontraditional*	Planned Start Date	Actual Start Date	Reason for Deviation from Plan

3.3 Plans for Next Quarter

- Major achievements planned for the next quarter

MEMORANDUM: Agreements Officer Representative Sign-Off

To: Agreements Officer Representative (AOR) From: ___
Date: ___
Reference: (a) MCDC Base Agreement between ATI and
___ Agreement No. ___
(b) Project Agreement No. ___
Subject: Milestone Approval

The following deliverable(s) associated with the Milestone(s) listed below have been completed:

MS#	Deliverable
XX	___

It is requested that verification of these accomplishments be provided to the MCDC Consortium Management Firm.

To: MCDC Consortium Management Firm

CERTIFICATION BY AGREEMENTS OFFICER REPRESENTATIVE:

The Project Agreement Holder has made satisfactory progress and provided the required deliverables associated with this milestone. I certify the work performed is in accordance with the approved Statement of Work (SOW) included in the agreement.

Other comments or concerns regarding this or future milestones:

[Note: For any non-satisfactory areas include a discussion of what was not acceptable, references to previous correspondence on the issue, and what corrective actions are needed to effect payment.]

_____ _____
Agreements Officer Representative Date:

Attachment C
Technical Direction Letter (TDL) RPP-20-08 Regeneron

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DEPARTMENT OF THE ARMY
U.S. ARMY CONTRACTING COMMAND – NEW JERSEY PICATINNY ARSENAL, NEW JERSEY 07806-5000

REPLY TO ATTENTION OF

06 July 2020

Army Contracting Command – New Jersey ACC-NJ, Building 9
Picatinny Arsenal, NJ 07806

SUBJECT: Technical Direction Letter for Medical CRBN Defense Consortium (MCDC), Request for Prototype Proposals (RPP) 20-08, Objective TRE-PRE-20-08 for "Large-Scale Manufacturing of Antibodies Directed to SARS-CoV-2" (Regeneron Pharmaceuticals, Inc.)

REF: Regeneron Request for Technical Direction Letter, RPP 20-08 under OTA W15QKN-16-9- 1002 for Objective TRE-PRE-20-08, dated 30 June 2020

Advanced Technology International ATTN: Sr. Contracts
Manager
315 Sigma Drive

Summerville, SC 29486 Dear ,

The Army Contracting Command – New Jersey (ACC-NJ), in supporting the Joint Project Manager – Medical Countermeasure Systems (JPM-MCS), issued MCDC RPP 20-08 on 17 May 2020. Members of the MCDC submitted proposals in accordance with this RPP. The Government received and evaluated all proposal(s) submitted and a Basis of Selection has been executed, selecting Regeneron as the awardee. The Government requests that a Firm-Fixed-Price Project Agreement be issued to Regeneron to award this proposal under Other Transaction Agreement W15QKN-16-9- 1002, to be performed in accordance with the attached Government Statement of Work (SOW).

Based upon the acceptable update of Regeneron's proposal for "Large-Scale Manufacturing of Antibodies Directed to SARS-CoV-2" and 1) The Project Agreement Recipient's concurrence with the requirements included in the Government SOW; 2) An acceptable milestone schedule that meets SOW requirements, and; 3) The cost proposal that has been analyzed and negotiated by the Government, you are hereby directed to issue a Project Agreement to Regeneron for the subject project. The total project value has been determined fair and reasonable and Regeneron's proposal has been selected IAW the above referenced Basis of Selection.

The total approved cost to the Government for this effort is not to exceed $450,392,000.00. The break-out of the costs is as follows: $450,262,000.00 to perform project efforts included in the SOW and $130,000.00 for the Consortium Management Firm (CMF) Administrative Cost. The CMF Administrative Cost and Fee was approved as a "Special Allocation" for Operation Warp Speed (OWS) Prototype Projects executed under the MCDC OTA. The effort currently has $450,392,000.00 of available funding, comprised of $450,262,000.00 for the Project Agreement and $130,000.00 for the CMF. PAH COVID-19 work shall be tracked separately using the funding obligated via modification P00074. In alignment with the special allocation conditions, it is noted that this project has a period of performance of twelve (12) months, with a projected completion date of 30 June 2021. A customized clause for the special allocation, will be incorporated into the funding modification for this prototype project.

The PAH is considered a small business, nontraditional defense contractor, or nonprofit research institution and determined to be providing a significant contribution. The affirmation of business status certifications submitted as part of the proposal are hereby incorporated into the agreement. The contractor shall notify the MCDC CMF of any deviation from the final proposed affirmation of business status certifications that would affect the contributions of the small business, nontraditional defense contractor, or nonprofit research institution as proposed.

In accordance with 10.U.S.C. 2371b(f), and upon a determination that the prototype project for this transaction has been successfully completed, this competitively awarded prototype OTA may result in the award of a follow-on production contract or transaction without the use of competitive procedures.

The Government and Advanced Technology International (“ATI”) hereby agree and confirm that (a) ATI, in its capacity as the Consortium Management Firm under the Medical CBRN Defense Consortium (MCDC) Other Transaction Agreement No. W15QKN-16-9-1002 (the MCDC Agreement), has the authorization to enter into the Medical CBRN Defense Consortium Base Agreement No. 2020-504 and the Statement of Work (collectively, the “Regeneron Agreement”) with Regeneron on behalf of the Government, (b) the Government is and shall be bound by its obligations set forth in the Regeneron Agreement, and the MCDC Agreement is hereby amended to incorporate these obligations in the MCDC Agreement, as that Agreement relates to Regeneron, and (c) Regeneron is an intended third-party beneficiary of such obligations that can enforce them directly against the Government, and (d) in the event of any conflict between the Regeneron Agreement, on the one hand, and the MCDC Agreement, on the other hand, the Regeneron Agreement shall control and take precedence.

Points of Contact:

Agreements Specialist:
E-mail:
Phone:

Agreements Officer:
E-mail:
Phone:

Regards,

Agreements Officer
Signed by:

Attachments:
Attachment 1: MCDC2008-005 - Regeneron - 7-3-2020 Attachment 2: OPSEC Language Addendum
Attachment 3: MCDC OTA Special Allocation Letter

_____
ATI Signatory

Advanced Technology International

Applied Technologies Center
315 Sigma Drive
Summerville, SC 29486
www.ati.org

October 13, 2020

Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Rd
Tarrytown, NY 10591

Attention:

Subject: Modification No. 01 to Project Agreement No. 01; MCDC2008-005

Reference: MCDC Base Agreement No. 2020-504

Dear :

In accordance with the terms and conditions of the referenced MCDC Base Agreement, Modification No. 01 hereby amends the Project Agreement No. 01 as follows:

DESCRIPTION OF MODIFICATION

1) The Technical and Administrative Representatives clause of the Project Agreement is hereby amended to read as indicated in bold below:

9. TECHNICAL AND ADMINISTRATIVE REPRESENTATIVES
The following technical and contractual representatives of the Parties are hereby designated for this Project Agreement. Either party may change their designated representatives by written notification to the other.

MCDC CMF Contractual Representative:
MCDC Contracts
Advanced Technology International
315 Sigma Drive
Summerville, SC 29486
Email:
Phone:

Government Technical Representatives:

Agreements Officer Representative (AOR):	**Alternate AOR:**
Email:	**Email:**
Phone:	**Phone:**

Project Agreement Holder's Representatives:

Technical Representative:	Contractual Representative:
777 Old Saw Mill River Rd	777 Old Saw Mill River Rd
Tarrytown, NY 10591	Tarrytown, NY 10591
Email:	Email:
Phone:	Phone:

2) The Attachments clause of the Project Agreement is hereby amended to **read as indicated in bold below:**

12. ATTACHMENTS

Attachments listed herein are hereby incorporated by reference into this Project Agreement.

A. Statement of Work, "Large-Scale Manufacturing of Antibodies Directed to SARS-CoV-2"
B. Report Requirements
C. Technical Direction Letter (TDL) RPP-20-08 Regeneron
D. Prohibition on the Use of Certain Telecommunications and Video Surveillance Services or Equipment

3) Attachment D, Prohibition on the Use of Certain Telecommunications and Video Surveillance Services or Equipment is hereby incorporated as attached herein.

Except as provided herein, all Terms and Conditions of the referenced MCDC Base Agreement, Project Agreement, and preceding modifications remain unchanged and in full force and effect.

The Project Agreement Holder is required to sign this document and return to Advanced Technology International to finalize this action.

Regeneron Pharmaceuticals, Inc.	**Advanced Technology International**
By: /s/ Robert Landry	By: /s/
Name: Robert Landry	Name:
Title: Executive Vice President, Chief Financial Officer	Title:
Date: November 12, 2020	Date: Nov 12 2020

Attachment D
Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment
Incoporated via Modification No. 01

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Attachment D

Prohibition on the Use of Certain Telecommunications and Video Surveillance Services or Equipment.

This Article is to ensure compliance with Section 889 of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232).

Based on the information provided below, the Government may be unable to enter into a new project agreement, exercise an option under an existing project, bilaterally modify a project agreement to extend the term of a project, execute an additional phase, or incrementally fund an existing project with the Member.

A. Definitions

Backhaul means intermediate links between the core network, or backbone network, and the small subnetworks at the edge of the network (*e.g.*, connecting cell phones/towers to the core telephone network). Backhaul can be wireless (e.g., microwave) or wired (*e.g.*, fiber optic, coaxial cable, Ethernet).

Covered foreign country means The People's Republic of China.

Covered telecommunications equipment or services means–

(1) Telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities);

(2) For the purpose of public safety, security of Government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities);

(3) Telecommunications or video surveillance services provided by such entities or using such equipment; or

(4) Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise connected to, the Government of a covered foreign country.

Critical technology means–

(1) Defense articles or defense services included on the United States Munitions List set forth in the International Traffic in Arms Regulations under subchapter M of chapter I of title 22, Code of Federal Regulations;

(2) Items included on the Commerce Control List set forth in Supplement No. 1 to part 774 of the Export Administration Regulations under subchapter C of chapter VII of title 15, Code of Federal Regulations, and controlled-

(i) Pursuant to multilateral regimes, including for reasons relating to national security, chemical and biological weapons proliferation, nuclear nonproliferation, or missile technology; or

(ii) For reasons relating to regional stability or surreptitious listening;

(3) Specially designed and prepared nuclear equipment, parts and components, materials, software, and technology covered by part 810 of title 10, Code of Federal Regulations (relating to assistance to foreign atomic energy activities);

(4) Nuclear facilities, equipment, and material covered by part 110 of title 10, Code of Federal Regulations (relating to export and import of nuclear equipment and material);

(5) Select agents and toxins covered by part 331 of title 7, Code of Federal Regulations, part 121 of title 9 of such Code, or part 73 of title 42 of such Code; or

(6) Emerging and foundational technologies controlled pursuant to section 1758 of the Export Control Reform Act of 2018 (50 U.S.C. 4817).

Interconnection arrangements means arrangements governing the physical connection of two or more networks to allow the use of another's network to hand off traffic where it is ultimately delivered (*e.g.*, connection of a customer of telephone provider A to a customer of telephone company B) or sharing data and other information resources.

Reasonable inquiry means an inquiry designed to uncover any information in the entity's possession about the identity of the producer or provider of covered telecommunications equipment or services used by the entity that excludes the need to include an internal or third-party audit.

Roaming means cellular communications services (*e.g.*, voice, video, data) received from a visited network when unable to connect to the facilities of the home network either because signal coverage is too weak or because traffic is too high.

Substantial or essential component means any component necessary for the proper function or performance of a piece of equipment, system, or service.

B. Prohibition

(1) The Member is prohibited from providing to the Government any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless the Member is providing (i) a service that connects to the facilities of a third-party, such as backhaul, roaming, or interconnection arrangements; or (ii) telecommunications equipment that cannot route or redirect user data traffic or permit visibility into any user data or packets that such equipment transmits or otherwise handles, or the covered telecommunication equipment or services. A waiver, for a period not exceeding August 13, 2021, may be requested.

(2) The Member acknowledges and accepts that the Government is prohibited from entering into a new project agreement, exercising an option under an existing project, bilaterally modifying the project agreement to extend the term of a project, executing an additional phase, incrementally funding an existing project with the member or with an entity that uses any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless an exception at paragraph (b)(1) of this article applies, regardless of whether that use is in performance of work under a Federal contract or agreement.

C. Certification (to be completed upon Agreements Officer Request)

The Member shall review the list of excluded parties in the System for Award Management (SAM) (https://www.sam.gov) for entities excluded from receiving federal awards for “covered telecommunications equipment or services.”

Based on that review:

(1) ☐ The Member certifies that it does ☐ does not ☐ provide covered telecommunications equipment or services as a part of its offered products or services to the Government in the performance of any contract, subcontract, other transaction agreement, or other contractual instrument.

(2) If the Member does provide covered telecommunications equipment or services as a part of its offered products or services to the Government in the performance of any contract, subcontract, other transaction agreement, or other contractual instrument as described in paragraph (c)(1), the Member certifies that it will ☐ will not ☐ provide covered telecommunications equipment or services to the Government in the performance of any contract, subcontract, other transaction agreement, or other contractual instrument resulting from this solicitation. If the Member will provide covered telecommunications equipment or services to the Government in the performance of

any contract, subcontract, other transaction agreement, or other contractual instrument resulting from this solicitation (C)(2), the Member shall provide the additional di clo ure information required at para raph (D)(1) of thi Article

(3) The Member certifies, after conducting a reasonable inquiry, for purposes of this certification, that it does □ does not □ use covered telecommunications equipment or services, or use any equipment, system, or service that uses covered telecommunications equipment or services. If the Member does use covered telecommunications equipment or services, or use any equipment, system, or service that uses covered telecommunications equipment or services as described under this paragraph (C)(3), the Member shall provide the additional disclosure information required at paragraph (D)(2) of this Article.

D. Disclosures

(1) Disclosure for the certification in paragraph (C)(2) of this Article. If the Member does provide covered telecommunications equipment or services to the Government in the performance of any contract, subcontract, other transaction agreement, or other contractual instrument in in paragraph (C)(2) of this provision, the Member shall provide the following information:

(i) For covered equipment—

a) The entity that produced the covered telecommunications equipment (include entity name, unique entity identifier, Commercial and Government Entity (CAGE) code, and whether the entity was the Original Equipment Manufacturer (OEM) or a distributor, if known);
b) A description of all covered telecommunications equipment offered (include brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); and
c) Explanation of the proposed use of covered telecommunications equipment and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (B)(1) of this Article.

(ii) For covered services—

a) If the service is related to item maintenance: A description of all covered telecommunications services offered (include on the item being maintained: Brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); or
b) If not associated with maintenance, the Product Service Code (PSC) of the service being provided; and explanation of the proposed use of covered telecommunications services and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (B)(1) of this Article.

(2) If the Member does use covered telecommunications equipment or services, or use any equipment, system, or service that uses covered telecommunications equipment or services in in paragraph (C)(3) of this Article, the Member shall provide the following information:

(i) For covered equipment—

a) The entity that produced the covered telecommunications equipment (include entity name, unique entity identifier, CAGE code, and whether the entity was the OEM or a distributor, if known);
b) A description of all covered telecommunications equipment offered (include brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); and
c) Explanation of the proposed use of covered telecommunications equipment and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (B)(2) of this Article.

(ii) For covered services—

a) If the ervice i related to item maintenance A de cription of all covered telecommunication ervice offered (include on the item being maintained: Brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); or

b) If not associated with maintenance, the PSC of the service being provided; and explanation of the proposed use of covered telecommunications services and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (B)(2) of this Article.

E. Reporting Requirement

(1) In the event the Member identifies covered telecommunications equipment or services used as a substantial or essential component of any system, or as critical technology as part of any system, during agreement performance, or the Member is notified of such by a subcontractor at any tier or by any other source, the Member shall report the information in paragraph (E)(2) of this Article to the Agreements Officer and to the Department of Defense website at https://dibnet.dod.mil. The Member must notify the CMF that a report has been made.

(2) The Member shall report the following information pursuant to paragraph (E)(1) of this clause:

(i) Within one (1) business day from the date of such identification or notification: the agreement number; the order number(s), if applicable; supplier name; supplier unique entity identifier (if known); supplier CAGE code (if known); brand; model number (original equipment manufacturer number, manufacturer part number, or wholesaler number); item description; and any readily available information about mitigation actions undertaken or recommended.

(ii) Within ten (10) business days of submitting the information in paragraph (E)(2)(i) of this clause: any further available information about mitigation actions undertaken or recommended. In addition, the Member shall describe the efforts it undertook to prevent use or submission of covered telecommunications equipment or services, and any additional efforts that will be incorporated to prevent future use or submission of covered telecommunications equipment or services.

F. Subcontracts

The Member shall insert the substance of this article, including this paragraph (F) and excluding paragraph (B)(2), in all subcontracts and other contractual instruments, including subcontracts for the acquisition of commercial items.

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT, MARKED BY BRACKETS, WERE OMITTED BECAUSE THOSE PORTIONS ARE NOT MATERIAL AND WOULD BE COMPETITIVELY HARMFUL TO THE COMPANY IF PUBLICLY DISCLOSED.

Applied Technologies Center
315 Sigma Drive
Summerville, SC 29486
www.ati.org

November 17, 2020

Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Rd
Tarrytown, NY 10591

Attention:

Subject: Modification No. 02 to Project Agreement No. 01; MCDC2008-005

Reference: MCDC Base Agreement No. 2020-504

Dear :

In accordance with the terms and conditions of the referenced MCDC Base Agreement, Modification No. 02 hereby amends the Project Agreement No. 01 as follows:

DESCRIPTION OF MODIFICATION

1) The Term of the Project Agreement clause is hereby amended as indicated in bold below:

2. TERM OF THE PROJECT AGREEMENT
The period of performance for this Project Agreement is from July 6, 2020 through **November 1, 2021** *(this is a four month extension).*

2) The Total Firm Fixed Price clause of the Project Agreement is hereby replaced with the Project Agreement Ceiling clause as indicated below:

4. PROJECT AGREEMENT CEILING
The total Project Agreement Ceiling for the services to be provided by the Project Agreement Holder is as follows:

	PROJECT AGREEMENT CEILING
Total Firm Fixed Price	[* * *]
Total Cost Reimbursable	[* * *]
Total Project Agreement Ceiling	**$465,861,635** *(this is an increase of $15,599,635)*

3) The Total Funding clause of the Project Agreement is hereby amended as indicated in bold below:

5. TOTAL FUNDING
The total amount of funding currently available for payment and allotted to this Project Agreement is **$465,861,635** *(this is an increase of $15,599,635).*

4) The Health Resource Priority and Allocations Systems (HRPAS) clause of the Project Agreement is hereby incorporated as indicated below:

18. Health Resource Priority and Allocations Systems (HRPAS)
In order to ensure the success of the Project Agreement Holder's efforts, a priority rating is incorporated into the project agreement for the procurement of raw materials, consumables, repair parts, and major end item assemblies by the Project Agreement Holder under Title I of the HRPAS.

Priority Rating: Defense Production Act (DPA) Title I - "DO -HR"

Each rated order executed by the Project Agreement Holder must include the following:

(a) The priority rating: *DPA* Title I- "DO-HR";
(b) A required delivery date or dates. The words "immediately" or "as soon as possible" do not constitute a delivery date;
(c) The written signature on a manually placed order, or the digital signature or name on an electronically placed order, of an individual authorized to sign rated orders for the person placing the order; and
(d) A statement that reads in substance:

(I) This is a rated order certified for national defense use, and you are required to follow all the provisions of the Health Resources Priorities and Allocations System regulation at 45 CFR part IO1.

(2) If the rated order is placed in support of emergency preparedness requirements and expedited action is necessary and appropriate to meet these requirements, the following sentences should be added following the statement set forth in paragraph (d) (l) of this section:

i. This rated order is placed for the purpose of emergency preparedness. It must be accepted or rejected within two (2) days after receipt of the order if:

A. The order is issued in response to a hazard that has occurred; or
B. If the order is issued to prepare for an imminent hazard, as specified in HRPAS §101.33(e).

5) Attachment A, Statement of Work, of the Project Agreement is hereby amended as attached herein.

Except as provided herein, all Terms and Conditions of the referenced MCDC Base Agreement, Project Agreement, and preceding modifications remain unchanged and in full force and effect.

The Project Agreement Holder is required to sign this document and return to Advanced Technology International to finalize this action.

Regeneron Pharmaceuticals, Inc.	**Advanced Technology International**
By: /s/ Robert E. Landry	By: /s/
Name: Robert E. Landry	Name:
Title: Executive Vice President – Finance & CFO	Title:
Date: November 17, 2020	Date: Nov 18, 2020

Attachment A Statement
of Work
(Incorporated as of Modification No. 02)

This page intentionally left blank. See separate document for Attachment A.

Attachment A
Statement of Work
(Incorporated as of Modification No. 02; changes to Sections 1, 3, 4, 5, 6, 8, and 11 are indicated in bold italics.)
For
Large-Scale Manufacturing of Antibodies Directed to SARS-CoV-2

RPP #: RPP-20-08
Project Identifier: MCDC OTA 2008-005, W15QKN-16-9-1002
Consortium Member: Regeneron Pharmaceuticals, Inc.
Title of Proposal: Large-Scale Manufacturing of Antibodies Directed to SARS-CoV-2
Date Updated: November 10, 2020

1.0 INTRODUCTION, SCOPE, AND OBJECTIVES

A. Preamble

Regeneron Pharmaceuticals, Inc. (referred to herein as "Regeneron", "Offeror", "Contractor" or "Recipient") has demonstrated experience with rapid scale-up of biopharmaceutical programs. Our excellent history of receiving development scale processes from Research and Development (R&D) laboratories, and then expanding to clinical or commercial Good Manufacturing Practice (GMP) scale production, is well documented. Greater than 65 processes have been transferred since 2008 with a success rate of 100%. We have consistently demonstrated our ability to expedite the delivery of high quality, safe and efficacious products (Ebola therapeutic) in partnership with the Government (anti-MERS, anti-Ebola).
Fully human monoclonal antibodies (mAbs) are molecules with high potency, predictable Pharmacokinetics (PK), and limited off-target toxicity, and thus provide attractive types of therapeutics for emerging diseases. Importantly, we have repeatedly demonstrated that candidate mAb-based drugs to prevent and/or treat emerging infections, can be rapidly obtained from Regeneron's proprietary VelocImmune® mice. Further, our ability to concurrently generate isogenic cell lines that are optimized for rapid antibody scale up and manufacturing using our proprietary Chemistry, Manufacturing, and Controls (CMC) platform technologies, have facilitated both testing of our mAbs in preclinical models and subsequent development of these mAbs into drugs suitable for human testing. In the process of completing many of these activities we have collaborated with other entities (including BARDA, Research Institutes, Government Laboratories and Universities). Our manufacturing has been designed to be paired with our proprietary VelocImmune® R&D technology, that is a proven process to rapidly take a research concept from the bench, into large scale production, with the ability to deliver medicines to patients.

The Government has advised Regeneron that it is appropriate for the project described in this Project Agreement to be performed through the Medical CBRN Defense Consortium (MCDC), under the authority of the MCDC Other Transaction Agreement No. W15QKN-16-9-1002. Regeneron is amenable to performing the project pursuant to such authority, based on the advice of the Government, and due to the unprecedented circumstances of the Coronavirus Disease

2019 (COVID-19) pandemic and, accordingly, the parties have entered into this Project Agreement.

B. Overall Objectives and Scope

This project is defined by discrete work segments for the continuous manufacture of drug substance, formulated drug substance and filled, packaged and labeled drug product, in accordance with a mutually agreed schedule.

Pursuant to this project, Regeneron will manufacture and sell drug product to the applicable United States (U.S.) Federal Government agency, for distribution in the U.S.

In addition, Regeneron, as a service to the Government, will engage one or more third party service providers (each a "Distributor") to perform storage and distribution activities for such drug product for the Government, at the direction of the Government. The Government will be solely responsible to determine the allocation of product to end users and to communicate such allocation determinations to the Distributor. The Government agrees that Regeneron will not be involved in or responsible for any such determinations.

Regeneron may conduct such activities itself or through one or more of its affiliates, including Regeneron Healthcare Solutions, Inc. References to "Regeneron" will be deemed to include such affiliates. All manufacturing described herein will be compliant with Food and Drug Administration (FDA) current Good Manufacturing ***P***ractices (cGMP), as 21 CFR 210 and 211.

1.1 Introduction

The objective is to conduct the manufacturing production activities described in this proposal for prototypes consisting of novel, proprietary mAb therapeutics and prophylactics, to reduce pathology of COVID-19 disease and/or prevent development of disease when administered prophylactically. ***In addition, Regeneron will engage the Distributor to perform storage and distribution of the product for the Government, at the Government's direction and control.***

1.2 Scope

These manufacturing production activities will include manufacturing at-scale, filling and finishing, and storage and shipping of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)-specific monoclonal antibodies (referred to herein as the "prototype", the "prototype product", the "product" or "drug product") for treatment and/or prophylaxis against COVID-19.

1.3 Definition of the Prototype Project

Consistent with USG objectives, Regeneron will employ its proprietary manufacturing technology and processes, in a manner compliant with applicable laws and regulations, including 21 CFR 210 and 211 and***, to the extent applicable,*** the Drug Supply Chain Security Act, to manufacture the prototype product. This effort constitutes a prototype project because it will be used to evaluate the technical feasibility of manufacturing the prototype product during the ongoing COVID-19 pandemic. In addition, this is a prototype project because Regeneron will demonstrate, and prove-out the at-scale, multi-lot proprietary manufacturing activities of Regeneron in order to assess the feasibility of these activities to support the necessary quantity of

the prototype product to treat the U.S. population. Successful completion of the prototype project will demonstrate Regeneron's capability to (i) rapidly manufacture product, which can be further scaled-up to meet mutually agreed to surge requirements with little advance notification and (ii) facilitate the Government's ability to stockpile and distribute large quantities of the drug product to respond when needed, including for use in clinical studies, under an Emergency Use Authorization (EUA), or pursuant to other ***approval*** from the U.S. FDA. For clarity, any manufacturing and supply of drug product in excess of the specific quantities set forth in Section 4.0 of this Statement of Work, shall be subject to a separate mutual agreement between Regeneron and the Government.

The scope of effort supported by this agreement is further clarified in Section 1.4. It is important to note that nonclinical and clinical studies for the prototype are being conducted by Regeneron outside of this agreement. The results of those studies may be used to develop use case scenarios and, in turn, inform the USG's deployment strategy as it relates to product manufactured under this agreement; however, such results (including the degree to which the data are "positive" or "negative") shall not be a factor in this prototype project. ***It is also important to note that the distribution and storage services performed for the Government by the Distributor engaged by Regeneron, are not part of the prototype project.***

1.4 Objective

- Conduct its proprietary manufacturing production activities described in this proposal for prototypes consisting of novel, proprietary mAb therapeutics and prophylactics, to reduce pathology of COVID-19 disease and/or prevent development of disease when administered prophylactically.
- The prototypes will include one or more of the following, as mutually agreed between Offeror and the Government:
    - the mAbs known as REGN10987 and REGN10933, as a cocktail;
    - Other mAbs (as monotherapies or a cocktail) as agreed to by bilateral modification between Offeror and the Government.
- The deliverables will be the products listed above (i.e., REGN10987 and REGN10933), in the form of bulk formulated drug substance and/or filled and finished product in vials, as mutually agreed between Offeror and the Government, packaged and labeled drug product, results, reports and records associated with generation of data demonstrating quality and control. ***Other deliverables will include product storage and support for the Government's distribution activities to be provided at the Government's direction.***
- The products will be delivered in the form and quantity to be agreed between Offeror and the Government. It is expected that the prototypes will be stored by Offeror until such time as (a) they can be used for pre-clinical or clinical development purposes under an Investigational New Drug application (IND), or (b) upon the FDA's grant of an EUA under Section 564 of the Food, Drug and Cosmetic Act (FD&C Act), or full marketing approval under a full Biologics License Application (BLA) under Section 351(a) of the Public Health Service Act (PHSA). ***In the event the FDA grants an EUA, the product will be distributed by the Distributor pursuant to direction from the Government (i.e., the Government will direct the Distributor where the product is to be distributed and in what quantities, and Regeneron will not be responsible for, or involved in, such direction).***

1.5 Follow-on Activity

In accordance with 10.U.S.C. 2371b(f), and upon successful demonstration of the prototype, or at the accomplishment of particularly favorable or unexpected results achieved outside of this Agreement that would justify transitioning to production (e.g., EUA or BLA), additional at-scale manufacturing of up to 800,000 treatment courses, supported by a mutually agreed upon follow-on production contract or Other Transaction Agreement, may be awarded to Regeneron, without further competition, to partially or completely meet the USG objective of supplying a safe and effective COVID-19 therapeutic or prophylactic treatment courses to ensure nationwide access. For clarity, any manufacturing and supply of drug product in excess of the specific quantities set forth in Section 4.0 of this Statement of Work shall be subject to a mutually-agreed upon separate agreement between Regeneron and the Government. For further clarity, neither party shall be obligated to negotiate or enter into such a separate agreement for follow-on production.

During the performance of the prototype project, the Government and contractor may negotiate the scope and price of follow-on production.

2.0 APPLICABLE REFERENCES

Current Good Manufacturing Practices, 21 CFR 210, 211

3.0 REQUIREMENTS

3.1 Technical

- The Offeror’s technical approach is expected to be similar, but not duplicative, to its manufacturing activities under its current agreements with the Biomedical Advanced Research and Development Authority (BARDA), including contract # HHSO100201700016C, and will include the following:
    - Drug Substance, Formulated Drug Substance, Drug Product (DS/FDS/DP) quality and control.
        - Regeneron will apply statistical process analysis to continuously qualify in-process controls and release parameters.
        - The manufacturing process will be evaluated against parameters that are correlated to process performance and product quality. Ranges for the performance of each unit operation will be established through process development recommended ranges, the generation of statistical limits based on small-scale studies, and/or continuous commercial-scale manufacturing experience. These ranges will be monitored during the execution of quality and control, and are designed to ensure that the process is in a state of control and to ensure that the manufacturing process operates in a consistent and reproducible manner. The quality and control runs will also confirm that the process and product impurity profiles are within limits, demonstrate the consistent removal of impurities, and demonstrate that the process is capable of operating within acceptable microbiological control limits. Additional sampling and testing beyond

that needed to assess process performance, may be completed to further process understanding.

- *Intermediate Hold Time Validation*: Intermediate hold time validation to be performed via combination of at scale and small scale executions:
    - Microbial Control: Where appropriate, microbial control data from at scale hold time studies, will be leveraged from historical validation runs with molecules which have similar equipment and sanitization procedures.
    - Chemical Stability: Chemical stability will be demonstrated using data from laboratory scale hold time studies performed for each of the prototypes, using material obtained from in-process pools from the 10,000 L manufacturing executions.
- *Media, Feed and Buffer Mixing Validation*: Preparation of buffers and media will be validated at commercial-scale. These validation studies will demonstrate that the preparation process consistently produces solutions meeting predefined limits for parameters indicative of homogeneity, such as pH, conductivity, osmolality, and turbidity. Where vessels of equivalent design and construction exist within the manufacturing facility, validation of media and buffer preparation will be performed on one representative vessel on at least three consecutive and successful executions.
- *Medium Storage Validation*: Medium storage validation will be separated into preparation hold and post-filtration storage, and has two components: microbial control and chemical stability. Pre-filtration microbial control is specific to the raw materials and the environment, and post-filtration microbial control is specific to each storage container and the ability of the storage container to maintain a microbial free condition. Maximum storage times for medium solutions with respect to microbial control will be validated as necessary at commercial scale, through preparation and storage of medium for extended storage times pre- and post-filtration. Validation will be achieved by demonstrating microbial control for a number of consecutive attempts established in the relevant validation protocol. Solutions will be prepared, stored for defined periods and tested for bioburden and endotoxin. Chemical stability of medium may be performed at small-scale to demonstrate storage conditions maintain integrity of chemical components. Bracketing approaches may be used to cover the different feeds and medium used, provided the individual protocol justifies the bracket.
- *Buffer Storage Validation:* Buffer storage validation is separated into preparation hold and post-filtration storage, and has two components: microbial control and chemical stability. Preparation holds are dependent on the solution composition. The worst- case solution for growth is determined using a risk-based approach, and post-filtration microbial control is specific to each vessel and the ability of a vessel to maintain a microbial free condition. Maximum storage times for buffer solutions will be validated as necessary at commercial-scale for microbial control, through preparation and storage of a non-growth inhibiting buffer for

extended storage times pre- and post-filtration. Validation will be achieved by demonstrating microbial control for a number of consecutive attempts established by the protocol. Buffer hold validation in stainless steel vessels will require ongoing evaluation and monitoring; however, buffer hold validation in disposable bioprocess containers may be shortened, if appropriate, by a bracketing approach. Solutions will be prepared, held and monitored over time for bioburden, endotoxin. Chemical stability of buffers may be performed at small-scale to demonstrate that storage conditions maintain integrity of chemical components. Bracketing approaches may be used to cover the large number of buffers used, provided the individual protocol justifies the bracket.

- *Chromatography Column Sanitization and Storage Validation*: Any newly required studies will be performed to validate the cleaning and storage procedures for [* * *] chromatography columns used in the manufacture of the prototypes. In addition, the maximum allowable storage period following cleaning will be established for each of the chromatography resins.
- *Chromatography Column Cleaning Validation*: The efficacy of the solutions used to clean the chromatography columns will be examined as necessary over three consecutive executions during commercial scale manufacturing of each of the prototypes. The effectiveness of the cleaning procedures will be assessed by sampling the post cleaning (post-use) Water for Injection (WFI) flush effluent; at approximately [* * *] into the flush for bioburden and endotoxin levels (the purpose of which is to demonstrate microbial control). In addition, Total Organic Carbon (TOC) will be measured to verify the absence of lot to lot protein carry over.
- *Chromatography Column Storage Validation*: The efficacy of the solutions used to store the chromatography columns will be examined, as necessary, over three consecutive executions during commercial scale manufacturing of each of the prototypes. The effectiveness of the cleaning and storage procedures will be assessed by sampling the post storage (pre-use) WFI flush effluent for bioburden, endotoxin levels and TOC. The maximum allowable storage period for each column will be established based on the shortest of the three consecutive executions for which the column remained in the storage solution.
- *Establishment of In-Process Control (IPC) Program*: The IPC program will utilize Statistical Process Control (SPC) to monitor critical and general process parameters, and critical and general quality attributes for each lot manufactured. On completion of quality and control activities, the IPC development report will establish the set of parameters and attributes to be monitored, and justify appropriate action limits for each. Upon approval of the development report, a Process Performance Monitoring (PPM) Plan will be generated containing the list of IPCs, historical data, selection of monitoring tools and response to signal strategy, statistical summary, and visualization of the IPCs. The IPC development report and PPM Plan will be further updated as laboratory and production scale characterization and validation data is gained, once defined production

milestones are achieved, and then annually afterward. The annual updates will assess the overall state of process control and include process capability analysis and assessment of evidence of special cause variation for all applicable IPCs. Process data for individual lots will be monitored through [* * *] PPM meetings, where any trend signals are identified and responded to. These meetings will be attended by subject matter experts from departments including, but not limited to, [* * *]

- **Master Cell Bank (MCB) Genetic Characterization**: [* **]
- **Working Cell Bank (WCB) Genetic Characterization**: [* * *]
- **DS/FDS/DP Registration Stability**: Stability studies for DS/FDS/DP will be initiated and executed according to stability protocols, International Council for Harmonisation (ICH) guidelines and internal procedures. Quality and control lots will be stored and monitored at the routine long term storage condition per the Specification for [* * *]. Samples will also be stored and monitored at Accelerated [* * *] condition for 6 months, and Stress [* * *] condition for [* * *] for the evaluation and identification of degradation pathways of the molecule. Stability studies performed on the quality and control lots will support the shelf life of each prototype, and confirm that the manufacturing process is suitable for commercial-scale manufacture. All testing will be conducted in a GMP Quality Control (QC) Laboratory. Any Out of Specification (OOS) or Out of Trend (OOT) results will be investigated.
- **DS/FDS/DP Shipping Validation**: Shipping Validation by actual transport will be performed on the DS/FDS/DP of each prototype to cover a distance and duration that will exceed routine shipment to the intended fill site. Successful shipping validation of intended shipping lanes is based on the ability of the container to maintain the product at a specified temperature, to preserve product quality, and meet specifications.
- **DS/FDS/DP Photostability Studies**: To determine overall photosensitivity of DS/FDS/DP per ICH requirements, a study will be performed at [* * *] under [* * *] and [* * *] light. Samples will be oriented for maximum light exposure using container closures designed for direct exposure, immediate pack/marketing pack, and a foil covered control. Testing will then be performed on [* * *] sample sets for stability indicating attributes.
- **QC Reference Standard Production and Stability**: Reference standards for the individual DS/FDS/DP GMP lots will be generated according to internal standard operating procedures. The DS/FDS/DP for each prototype will be filled as a product reference standard. The first manufactured lot (lead lot) will be sub-aliquoted into single use vials, stored and routinely monitored at [* * *] by Offeror's Quality Control personnel. The reference standard will be qualified prior to use, according to specifications. A Certificate of Qualification (CofQ) will be issued for each individual reference standard at the time of initial qualification and following recertification testing. A stability study to monitor the critical quality attributes of each reference standard will also be conducted.
- **Assay Validation**: Will be performed as necessary to support any applicable EUA or other regulatory requirements.

- **Manufacturing**: Following the completion of the activities described above, Offeror will manufacture prototypes at scale in order to achieve the intended scope of the contract.
- **Label/Pack**: Labeling and packaging of investigational product for clinical studies or for use under an EUA or approval, will be completed at a GMP contract manufacturing organization managed by Offeror's External Manufacturing group.
- **Storage *and Distribution***: Packaged and labeled material storage will be managed by Offeror's External Manufacturing group ***and, if an EUA is granted, the Distributor will store and distribute the product at the direction of the Government (i.e., the Government will direct the Distributor as to where the product is to be distributed and in what quantities, and Regeneron will not be responsible for, or involved in, such direction). The process and obligations are illustrated in Figure 1 below***.

Figure 1 – Distribution Process:

[* * *]

3.2 Management and Reporting

3.2.1 Program Management

Below are the individuals currently assigned to key roles on the project team. Regeneron reserves the right to make personnel changes which will be communicated accordingly.

a. Regeneron will manage, integrate and coordinate all activities, including utilizing Regeneron's state-of-the-art technical and administrative infrastructure to ensure efficient planning, initiation, implementation and direction of contracted activities.

b. The [* * *], is responsible for guiding the project approach and scope of this Program.

c. [* * *], will serve as Lead PI for this Program. The PI will be responsible for project management, communication, tracking, monitoring and reporting on status and progress, and modification to the project requirements and timelines, including any projects undertaken by subcontractors.

d. A [* * *], will be responsible for monitoring and tracking day-to-day progress and timelines, coordinating communication and project activities, costs incurred, and program management for this Program. The contract deliverables list identifies all contract deliverables and reporting requirements for this contract.

e. [* * *], will provide development of compliant subcontracts, consulting, and other legal agreements.

f. [* * *], will be responsible for financial management and reporting on all activities conducted by Regeneron and any subcontractors.

g. A [* * *], will be responsible for facilitating the development of integrated CMC plans and for monitoring and tracking the progress of the CMC milestones.

h. A [* * *], will be responsible for management of batch disposition, oversight of discrepancy investigations, and to ensure all released product conforms to GMP standards.

i. A [* * *], will be responsible for analytical method development, method transfer and specification development.

j. A [* * *], will be responsible for ensuring Regeneron quality, preclinical, and clinical drug development programs are conducted in compliance with regulations governing pharmaceutical drug development, and with project specific regulatory commitments/requirements ,and will serve as the liaison for communications with the US Food and Drug Administration.

k. Regeneron shall provide Quarterly Progress Reports, which shall include a description of the activities during the reporting period and the activities planned for the ensuing reporting period.

l. Regeneron shall provide Annual Progress Reports, which shall include a summation of the activities during the reporting period, and the activities planned for the ensuing reporting period.

m. Regeneron shall provide Draft and Final Reports, which shall include a summation of the work performed and results obtained for execution of various studies or technical work packages during the entire contract period of performance. This report shall describe the results achieved.

n. Regeneron shall participate in regular meetings to coordinate and oversee the contract effort, as directed by a single point of contact established by the Government. Such meetings may include, but are not limited to, meetings of Regeneron and subcontractors to discuss clinical manufacturing progress, product development, scale-up manufacturing development, preclinical/clinical study designs and regulatory issues, meetings with individual contractors and other Health and Human Services (HHS) officials to discuss the technical, regulatory, and ethical aspects of the program, and meetings with technical consultants to discuss technical data provided by Regeneron. Regeneron shall also consult with the Government as required in connection with meetings and submissions to regulatory agencies, including the FDA. The Government will establish a single point of contact for regular meetings and coordinate all requests for information through such point of contact, such that Regeneron shall not be required to attend multiple meetings with different Government agencies for the same (or similar) subject matter, or respond to multiple requests for information or materials concerning the same (or similar) subject matter.

o. Regeneron shall participate in teleconferences at an agreed upon frequency between Regeneron and ***the Government*** to review technical progress.

3.2.2 Integrated Master Schedule (IMS)

Regeneron will provide an Integrated Master Schedule within [* * *] of the award, and shall update such schedule to reflect any material changes. Within an agreed upon timeframe of the effective date of the contract, Regeneron will make any agreed upon changes between Regeneron and Agreements Officer and/or Project Officer at the Government. The IMS shall be incorporated into the contract and will be used to monitor

performance of the contract. Regeneron shall include the key milestones and Go/No-Go decision gates. The IMS for the period of performance will be accepted by the Government [* * *] of the Government's receipt of such IMS.

3.2.3 Reporting

On completion of a stage of the product development, as defined in the agreed upon IMS and Integrated Master Plan, Regeneron shall prepare and submit to the Project Officer and the Agreements Officer, reports from time to time that contain (i) reasonable detail, documentation and analysis to support successful completion of the stage according to the predetermined qualitative and quantitative criteria, and (ii) a description of the next stage of product development to be initiated, and a request for approval to proceed to the next stage of product development.

3.2.4 Data Management

Regeneron will utilize existing systems to implement data management and quality control systems/procedures, including transmission, storage, confidentiality, and retrieval of contract data. Provide analysis of data generated with contract funding to the Project Officer or Agreements Officer, upon request.

3.2.5 Technical and Financial Reporting

Technical Reports are described in Section 3.3.1 k., l. and m. They are also listed in the milestone schedule and deliverables table in Section 5 of this Statement of Work.

For Financial Reporting, firm fixed price ***or cost-reimbursement*** invoices will be submitted on a quarterly ***or monthly*** basis, as described in Section 5 below. Invoices will include data and technical reports sufficient to support the accomplishment of each milestone, as appropriate, during the invoicing period. Regeneron will provide quarterly Financial Status Reports outlining billed vs. budgeted activity for each period, and in aggregate for the contract.

3.2.6 Product Development Manufacturing Reports and Projections

Regeneron will provide manufacturing reports and manufacturing dose tracking projections/actuals, in the format and having the content mutually agreed upon by the Government and Regeneron. Regeneron will update the reports* [* * *] *during manufacturing campaigns and upon manufacturing deliverable submission during COVID-19 response operations (where a Public Health Emergency has been declared), with the first deliverable submission within* [* * *] *of award/modification. For clarity, the reports described in this Section 3.2.6 apply to Formulated Drug Substance and Drug Product prior to delivery and acceptance by the Government. Tracking reports for product following delivery and acceptance, shall be set forth in the Memorandum of Understanding between Regeneron, the Distributor, and the Government.

4.0 DELIVERABLES

Offeror assumed [* * *]; Filled/Finished Drug Product Deliveries [* * *]. Regeneron shall have the right to provide deliverables directly to the Government and not to the Consortium Management Firm (CMF).

Deliverable Table (June 2020 - *November* 2021)

Deliverable	Due Date	Total Program Funds	Data Rights
Project Kick-Off; Deliverable	[* * *]	[* * *]	*Specially Negotiated
DS/FDS Bulk GMP Lot [* * *]	[* * *]	[* * *]	*Specially Negotiated
DS/FDS Bulk GMP Lot [* * *]	[* * *]	[* * *]	*Specially Negotiated
DS/FDS Bulk GMP Lot [* * *]	[* * *]	[* * *]	***Specially Negotiated***
DS/FDS Bulk GMP Lot [* * *]	[* * *]	[* * *]	***Specially Negotiated***
DS/FDS Bulk GMP Lot [* * *]	[* * *]	[* * *]	*Specially Negotiated
Fill Product [* * *]	[* * *]	[* * *]	*Specially Negotiated
Fill Product [* * *]	[* * *]	[* * *]	*Specially Negotiated
Fill Product [* * *]	[* * *]	[* * *]	*Specially Negotiated
Fill Product [* * *]	[* * *]	[* * *]	***Specially Negotiated***
Fill Product [* * *]	[* * *]	[* * *]	***Specially Negotiated***
Fill Product [* * *]	[* * *]	[* * *]	***Specially Negotiated***
Package/Label Product	[* * *]	[* * *]	*Specially Negotiated
Storage of Drug Product in VMI [* * *]	[* * *]	[* * *]	*Specially Negotiated
Storage of Drug Product in VMI [* * *]	[* * *]	[* * *]	*Specially Negotiated
Storage of Drug Product in VMI [* * *]	[* * *]	[* * *]	*Specially Negotiated
Storage of Drug Product in VMI [* * *]	[* * *]	[* * *]	*Specially Ne otiated
Support Distribution of Drug Product and [* * *]	[* * *]	[* * *]	***Specially Negotiated***
Quarterly Technical and Business Status Report, see above for submission schedule	[* * *]	[* * *]	*Specially Negotiated

Annual Technical and Business Status Report, see above for submission schedule	[* * *]	[* * *]	*Specially Negotiated
Quarterly Technical and Business Status Report, see above for submission schedule	[* * *]	[* * *]	*Specially Negotiated
[* * *]	[* * *]	[* * *]	Limited Rights
		$465,861,635* (FFP *and Cost Reimbursement)	

*Upon payment, delivery and acceptance in accordance with the terms of this Project Agreement, the Government will have title to the product produced under this Statement of Work. The Government will have the rights described below in Section 7.3 to technical data disclosed under this Statement of Work.

**Packaging and labeling of product will be performed following the determination of the use of the applicable drug product (e.g., for clinical trials or for distribution under an EUA or BLA).

******Total Program Funds for distribution and [* * *] is a not-to-exceed amount, and shall be invoiced as described in Section 5.0 below.***

*******If an EUA is granted, then the product shall be transferred from VMI to the Distributor for distribution, as directed by the Government, and the VMI storage milestones shall be equitably adjusted.***

5.0 MILESTONE PAYMENT SCHEDULE; TERMINATION COSTS

Milestone *No.*	**Milestone Description (Deliverable Reference)**	**Due Date**	**Total Program Funds**
5.1	[* * *] Drug Substance Deliverables ([* * *] of Drug Substance)	[* * *]	[* * *]
5.2	[* * *] Drug Substance Deliverables ([* * *] of Drug Substance)	[* * *]	[* * *]
5.3	[* * *] Drug Product Deliverables (Fill/Finish for [* * *] of Drug Substance)	[* * *]	[* * *]
5.4	[* * *] Drug Substance Deliverables ([* * *] of Drug Substance)	[* * *]	[* * *]
5.5	[* * *] Drug Product Deliverables (Fill/Finish for [* * *] of Drug Substance)	[* * *]	[* * *]
5.6	[* * *] ***Drug Substance Deliverables ([* * *] of Drug Substance)***	[* * *]	[* * *]
5.7	[* * *] ***Drug Product Deliverables (Fill/Finish for*** [* * *] ***of Drug Substance)***	[* * *]	[* * *]
5.8	[* * *] ***Drug Substance Deliverables ([* * *] of Drug Substance)***	[* * *]	[* * *]
5.9	[* * *] ***Drug Product Deliverables (Fill/Finish for*** [* * *] ***of Drug Substance)***	[* * *]	[* * *]
5.10	[* * *] ***Drug Product Deliverables (Fill/Finish for*** [* * *] ***of Drug Substance)***	[* * *]	[* * *]
5.11	Quarterly Technical and Business Status Report, Reference 3.3.1.k	[* * *]	[* * *]
5.12	Annual Technical and Business Status Report, Reference 3.3.1.l	[* * *]	[* * *]
5.13	Storage of Drug Product in VMI [* * *]	[* * *]	[* * *]
5.14	Storage of Drug Product in VMI [* * *]	[* * *]	[* * *]
5.15	Storage of Drug Product in VMI [* * *]	[* * *]	[* * *]
5.16	Storage of Drug Product in VMI [* * *]	[* * *]	[* * *]
5.17	***Support of Distribution of Drug Product and*** [* * *]	[* * *]	[* * *]
	Total (Include Payment Type; FFP/*CR*):		***$465,861,635***
	Period of Performance:		**June 2020 – *November 2021***

The overall price is a not-to-exceed price of $465,861,635, structured as a firm fixed price of **[* * *]** ***and a cost reimbursement budget (for support of distribution and*** **[* * *]** ***only) of*** **[* * *]**. ***Milestone payments will be made monthly or quarterly. The Parties acknowledge that deliverables for a given month or quarter may not correspond to the table above. In the event the deliverables in a given month or quarter are less than or exceed the projected quantity for such month or quarter, or in the event of a monthly invoice against an amount designated for a quarter in the table above, the milestone payment will be equitably adjusted based on the shortfall, excess or monthly amount, as applicable. With respect to the Distribution and*** **[* * *]**

milestone (5.17), Regeneron shall invoice against such milestone based on actual, external costs incurred by Regeneron during the applicable period, plus an allowance for Regeneron's general and administrative expense. Milestone payment terms will be net 30 days.

Total pricing ***for Drug Substance and Drug Product*** is a firm fixed price per lot, [* * *]. Regeneron will deliver [* * *] of filled/finished drug product. Regeneron will be entitled to full payment for drug product upon delivery/acceptance (as described herein) of filled/finished drug product, prior to packaging and labeling. However, Regeneron shall be responsible for the packaging and labeling of product at no additional cost following the determination of the use of such drug product (e.g., for clinical trials or for distribution under an EUA or BLA). Drug product will comply with the Drug Supply Chain Security Act serialization and tracking requirements***, unless waived or otherwise not applicable.*** Drug product will not be co-formulated, except as otherwise mutually agreed ***upon*** by the parties. Unless and until otherwise mutually agreed ***upon, approximately*** **[* * *]** ***of*** the drug product produced under this Statement of Work will be filled [* * *]**.** In order to change this allocation, Regeneron will require at least [* * *] prior written notice, in order to meet Regeneron's notification requirements to its fill/finish subcontractor. ~~***Regeneron will provide the Government with the timeline for fill/finish activities, including the dates by which the parties must determine the allocation of fill/finish activities.***~~ Notwithstanding the foregoing, as part of this Project Agreement, Regeneron will have the right to utilize material and capacity supported by this agreement ***of*** up to [* * *], as well as any additional drug product ***for such uses, as*** mutually agreed upon by Regeneron and the Government (with respect to which use the Government will not unreasonably withhold consent).

In the event this Statement of Work is terminated prior to completion, termination costs recoverable by Regeneron under Section 2.04 of the MCDC Base Agreement, shall include the following: the full contract price for any drug product manufactured and not yet paid for; a pro-rated portion of the contract price for drug substance or drug product that is in process, based on the stage of production; [* * *] raw materials that Regeneron purchased (or is obligated to purchase) that cannot be allocated to other products***;*** [* * *]**.**

6.0 *SALE*, STORAGE, AND SHIPPING PROVISIONS

Upon acceptance by the Agreements Officer Representative of any lot of antibodies under this contract, title to such antibodies will transfer as follows: upon delivery of drug product to vendor-managed inventory and the Government's corresponding written acceptance of the delivery of each such lot of drug product. The Government shall accept product that conforms to contract requirements based on a Certificate of Analysis (COA) provided by Regeneron***, and the parties shall perform their obligations relating to product delivery set forth in the applicable Quality Agreement for the product.*** The Government's acceptance of product will be [* * *] provide written notice of acceptance or rejection [* * *]. ***In the event of an EUA, Regeneron will transfer product from VMI to the Distributor for distribution directed by the Government; provided that, product shall not be provided to the Distributor until it is accepted by the Government.*** Unless otherwise mutually agreed upon by the parties, drug product shall be shipped to the Government ***or distributed, as applicable,*** within the continental United States. Regeneron will [* * *] for all product stored as vendor-managed inventory***, and while such product is in the possession of the Distributor and being distributed for the Government. With respect to product being distributed,*** **[* * *]** ***to the Government upon delivery from the Distributor to the end-user (e.g., the hospital, infusion center or other end-user).*** To the extent

that Regeneron is responsible for the correction, repair or replacement of Government property held in vendor-managed inventory ***or in distribution and in the possession of the Distributor,*** [* * *], the Government will [* * *] of such property. Vendor-managed storage of product manufactured under this agreement is supported through June 30, 2021 ***or, if an EUA is granted, for the 12-month period following an EUA. As such, if an EUA is not granted,*** the Government must either (a) take possession on or before ***June 30, 2021*** and provide Regeneron with disposition instructions in sufficient time to transfer physical material from Regeneron by this date, or (b) bilaterally modify this agreement to extend the period of vendor management of storage prior to this date. ***If an EUA is granted prior to June 30, 2021, then storage and distribution activities under the EUA shall be supported under this agreement for up to 12 months following the grant of an EUA, except that additional costs may apply (and the storage milestones shall be equitably adjusted) if storage of product as VMI is required following the end of June 30, 2021.***

The Government understands that prices identified in this contract include [* * *] applicable to material that will become Government property, including product stored as vendor-managed inventory ***or in the possession of the Distributor, and being distributed for the Government.***

7.0 PATENT RIGHTS; DATA RIGHTS; PREP ACT AND TRANSPARENCY

Article X, ("PATENT RIGHTS") and Article XI. ("DATA RIGHTS") of Other Transaction Agreement number W15QKN-16-9-1002 shall not apply to this Project Agreement and are hereby replaced for the purpose of this Project Agreement, with this Section 7.0 (including Sections 7.1-7.4 and the Definitions Appendix).
Definitions:

Capitalized terms used in this Section 7.0 (including Sections 7.1-7.4) shall have the meanings ascribed to such terms in the Definitions Appendix to this Project Agreement.

For purposes of this Project Agreement, all rights of the Government in and to Data or Subject Inventions are granted solely to The United States of America, as represented by the Department of Health & Human Services, Office of the Assistant Secretary for Preparedness & Response ("ASPR"), Office of Biomedical Advanced Research and Development ("BARDA") (represented by Office of Acquisition Management, Contracts and Grants (AMCG)) and to no other agency of the United States of America (including JPEO) or representative of any such other agency (including the CMF). The parties acknowledge that Regeneron is permitted to communicate solely with BARDA regarding the matters described in this Section 7.0 (including Sections 7.1-7.4) and is not obligated to communicate with any other Government agency or representative regarding such matters.

7.1 BACKGROUND INTELLECTUAL PROPERTY

Each party acknowledges that it has no rights to the other party's inventions, discoveries, know-how, Data, technology or intellectual property generated, discovered, conceived or reduced to practice prior to or otherwise outside of this Statement of Work (also referred to herein as, this "Project Agreement" or this "Agreement"), and any improvements or modifications thereto, including, without limitation, the background intellectual property (and improvements/modifications) for the Government and Regeneron described below, as follows:

Government Background Intellectual Property. None.

Contractor Background Intellectual Property: Includes, but is not limited to, [* * *]:

63/004,312, filed April 2, 2020 “Anti-SARS-CoV-2-Spike Glycoprotein Antibodies and Antigen-Binding Fragments”

[* * *]

63/014,687, filed April 23, 2020 “Anti-SARS-CoV-2-Spike Glycoprotein Antibodies and Antigen-Binding Fragments”

[* * *]

63/025,949, filed May 15, 2020 “Anti-SARS-CoV-2-Spike Glycoprotein Antibodies and Antigen-Binding Fragments”

[* * *]

[* * *]

63/034,865, filed June 4, 2020 “Anti-SARS-CoV-2-Spike Glycoprotein Antibodies and Antigen-Binding Fragments”

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No party relinquishes rights in any of its background intellectual property to any other party under this contract.

Either Party may update its disclosure of background intellectual property under this Section 7.1 upon written notice to the other Party.

7.2 PATENT RIGHTS

a. Allocation of Principal Rights

The parties agree that the Bayh-Dole statute does not apply to this Project Agreement. Ownership of inventions Made in the performance of this Project Agreement shall follow inventorship, and inventorship shall be determined in accordance with United State patent law With re pect to any Subject Invention Made (in whole or in part) by or on behalf of Re eneron, unle Regeneron shall have notified the Government (in accordance with Subparagraph b. below) that Regeneron does not intend to properly disclose and elect title to a Subject Invention, Regeneron shall retain the entire right, title, and interest throughout the world to such Subject Invention, and the Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the Subject Invention

throughout the world. This license does not include the right to use or allow others to use the Subject Invention for commercial purposes. If Regeneron does not properly disclose and elect title to any such Subject Invention (in accordance with Subparagraph b. below), then the Government may exercise its rights to seek ownership of such Subject Invention, pursuant to clause 7.2.c. below.

b. Invention Disclosure, Election of Title, and Filing of Patent Application

i. Regeneron shall disclose in writing each Subject Invention to the OTTR within 12 months after the inventor discloses it in writing to Regeneron personnel responsible for patent matters. The disclosure shall identify the inventor(s) and this Project Agreement under which the Subject Invention was made. It shall be sufficiently complete in technical detail to convey a clear understanding of the Subject Invention. The disclosure shall also identify any publication, on sale (i.e., sale or offer for sale), or public use of the Subject Invention, or whether a manuscript describing the Subject Invention has been submitted for publication and, if so, whether it has been accepted for publication. In addition, after disclosure to the Government funding agency (HHS/BARDA), Regeneron shall promptly notify the OTTR of the acceptance of any manuscript describing the Subject Invention for publication and any on sale or public use.

ii. Regeneron shall elect in writing whether or not to retain ownership of any Subject Invention by notifying the OTTR within 2 years of disclosure to the Government funding agency. However, in any case where publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, the period for election of title may be shortened by the agency to a date that is no more than 60 calendar days prior to the end of the statutory period.

iii. Regeneron shall file either a provisional or a non-provisional patent application for an elected Subject Invention within 1 year after election of title. However, in any case where a publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, Regeneron shall file the application prior to the end of that statutory period. If Regeneron files an initial provisional application, it shall file a non-provisional application within 10 months of the filing of the initial provisional application. Regeneron shall include a Government Support Clause (GSC) within the specification of any United States patent applications and any patent issuing thereon covering a subject invention.

iv. Regeneron may request extensions of time for disclosure, election, or filing under subparagraphs (b)(i), (b)(ii) and (b)(iii) of this clause. An extension of time for each deadline, may be granted at the discretion of the Government funding agency.

v. If Regeneron determines that it does not intend to elect to retain title to any such Subject Invention, Regeneron shall notify the Government, in writing, within two (2) years of disclosure to the Government. However, in any case

where publication, sale, or public use has initiated the one (1)-year statutory period wherein valid patent protection can still be obtained in the United States, the period for such notice may be shortened by the Government to a date that is no more than sixty (60) calendar days prior to the end of the statutory period.

c. Conditions When the Government May Obtain Title

Upon the Government's written request, Regeneron shall convey title to any Subject Invention to the Government funding agency if Regeneron fails to disclose the Subject Invention or elects not to retain title to the Subject Invention within the times specified in Subparagraph b of Section 7.2. The Government may request title after learning of the failure of Regeneron to disclose or elect within the specified times for an unlimited time. The Government funding agency may request title upon Regeneron's omission to timely file patent applications in any country. The Government funding agency may request title in any country in which Regeneron decides to discontinue prosecution.

d. Rights to Regeneron and Protection of Regeneron's Right to File

Regeneron shall retain a fully paid up, sub-licensable, nonexclusive, royalty-free license throughout the world in each Subject Invention to which the Government obtains title. Regeneron license extends to Regeneron's subsidiaries and other affiliates (outside this Agreement), if any, within the corporate structure of which Regeneron is a party and includes the right to grant licenses of the same scope to the extent that Regeneron was legally obligated or permitted to do so at the time the Project Agreement was executed. The license is otherwise transferable only with the approval of the Government, except when transferred to an Affiliate or successor of that part of Regeneron's business to which the Subject Invention pertains. The Government approval for license transfer shall be provided on a timely basis (and in no event later than 90 calendar days following Regeneron's request) and shall not be unreasonably withheld.

i. The Regeneron license may be revoked or modified by the Government to the extent necessary to achieve expeditious Practical Application of the Subject Invention pursuant to an application for an exclusive or nonexclusive license submitted consistent with appropriate provisions at 37 CFR Part 404. Regeneron's license shall not be revoked in that field of use or the geographical areas in which Regeneron has achieved Practical Application of the Subject Invention and continues to make the benefits of the Subject Invention accessible to the public.

ii. Before revocation or modification of Regeneron's license, the Government shall furnish Regeneron with a written notice of its intention to revoke or modify the license, which notice shall include a detailed explanation of the reasons for such revocation or modification, and Regeneron shall be allowed thirty (30) calendar days (or such other time as may be authorized for good cause shown) after the notice to show cause why the license should not be revoked or modified.

e. Action to Protect the Government's Interest

Regeneron agrees to execute or to have executed and promptly deliver to the Government all instruments necessary to (i) establish or confirm the rights the Government has throughout the

world in those Subject Inventions to which Regeneron elects to retain title, and (ii) convey title to the Government when requested under Subparagraph c of this Section 7.2 and to enable the Government to obtain patent protection throughout the world in that Subject Invention.

i. Regeneron agrees to require, by written agreement, its employees, other than clerical and non-technical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by Regeneron, each Subject Invention made under this Agreement so Regeneron can comply with the disclosure provisions of this Section 7.2. Regeneron shall use reasonable efforts to instruct employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

ii. Regeneron shall notify the Government of any decisions not to continue the prosecution of a patent application for a Subject Invention, pay maintenance fees, or defend in a reexamination or opposition proceedings on a patent of a Subject Invention, in any country, not less than thirty (30) calendar days before the expiration of the response period required by the relevant patent office.

Regeneron shall include, within the specification of any United States patent application and any patent issuing thereon covering a Subject Invention, the following statement: “This invention was made with Government support under Agreement **MCDC2020-504**, awarded by the U.S. Department of Health and Human Services. The Government has certain rights in the invention.”

f. Lower Tier Agreements

Regeneron shall ensure that its Affiliate agreements and Sub-Recipient Agreements regardless of tier, for experimental, developmental, or research work entered into after the Effective Date and submitted for reimbursement under this Agreement, contain invention reporting and assignment requirements sufficient to permit Regeneron to comply with this Section 7.2.

g. Reporting on Utilization of Subject Inventions

i. Regeneron agrees to submit, during the term of this Project Agreement, an annual report on the utilization of a Subject Invention or on efforts at obtaining such utilization that is being made by Regeneron or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commercial sale or use, and such other data and information as the agency may reasonably specify. Regeneron also agrees to provide additional reports as may be requested by the Government in connection with any march-in proceedings undertaken by the Government in accordance with Subparagraph h of this Section 7.2. Consistent with 35 U.S.C. § 202(c)(5), the Government agrees it shall not disclose such information to persons outside the Government without permission of Regeneron.

ii. All required reports shall be submitted to the e-room, OTAS, OTAO, and OTTR.

h. Compulsory Licensing Rights

Regeneron agrees that, with respect to any Subject Invention in which it has retained title, the Government has the right to require Regeneron, an assignee, or exclusive licensee of a Subject Invention to grant a non-exclusive license to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if Regeneron, assignee, or exclusive licensee refuses such a request, the Government has the right to grant such a license within the Field itself *only* if the Government determines that:

i. Action is necessary to alleviate the following health or safety needs that may affect the United States and Regeneron (itself or through its assignee, subcontractor or licensee) is unwilling or unable to manufacture or supply the Subject Invention to address such needs:
   a. Declaration for Public Health Emergency by the Secretary of HHS;
   b. Determination that there is a significant potential for a public Health emergency that has a significant potential to affect a national or health security of U.S. citizens as determined by the Secretary of HHS; or
   c. Declaration by WHO Director General of a public health emergency of international concern.

7.3 DATA RIGHTS

a. Allocation of Principal Rights

i. For Data produced under this SOW including Computer Software, to the extent developed with Government funds provided under this SOW, except as expressly provided elsewhere in this Project Agreement (including Section 7.3.b.), Regeneron grants to the Government a paid-up, nonexclusive, nontransferable, irrevocable, worldwide license in such Data (a) to exercise Government Purpose Rights for a period of ten (10) years following the production of such Data, (b) to exercise Unlimited Rights following the expiration of such ten (10)- year period. For Data produced under this Project Agreement, excluding Computer Software, to the extent developed with private funds and for other Data designated by Regeneron as “Limited Rights Data”, Regeneron grants to the Government a paid-up, nonexclusive, nontransferable, irrevocable, worldwide license in such Data to exercise Limited Rights. The Government will not obtain any rights in Computer Software produced under this Project Agreement to the extent developed with private funds. For certificates of analysis and batch records pertaining to drug product purchased under this Project Agreement, the Government shall have Unlimited Rights.

ii. Regeneron agrees to retain and maintain in good condition all Data produced under this Project Agreement and necessary to achieve Practical Application of any Subject Invention in accordance with Regeneron’s established record retention practices. In the event of an exercise of the Government’s compulsory licensing rights as set forth under Section

7.2.h., Regeneron agrees, upon written request from the Government, to deliver at no additional cost to the Government, all existing Data produced under this Project Agreement necessary to achieve Practical Application of the relevant Subject Invention within sixty (60) calendar days from the date of the written request.

iii. Regeneron's right to use Data is not restricted and includes the right under Regeneron's established business policies to make public research Data (especially human research Data) by publication in the scientific literature, by making trial protocols, trial results summaries, and clinical studies reports publicly available, and by making trial patient-level data available for third-party analysis.

b. Proprietary Manufacturing Data

Notwithstanding anything to the contrary in this Project Agreement, Regeneron retains all rights in and to Data relating to or comprising Regeneron's proprietary manufacturing technology and processes, including any trade secrets, Chemistry, Manufacturing and Controls information (CMC Data), and Data concerning or arising from test method development, device or delivery system development, assay development, formulation, quality assurance/quality control development, technology transfer, process development and scale-up and cell-line development, and the Government shall have no rights to use such Data independently from this Agreement or to disclose such Data to any third party. Regeneron may designate certain Data concerning it manufacturing activitie a Limited Ri ht Data, in which ca e the Government hall have Limited Ri ht in and to uch Data Regeneron will use reasonable efforts to mark any Limited Rights Data delivered under this Project Agreement with appropriate Limited Rights markings.

c. Identification and Disposition of Data

Regeneron shall keep copies of all Data relevant to this Project Agreement as required by the Food and Drug Administration (FDA) for the time specified by the FDA. The Government reserves the right to review any other data determined by the Government to be relevant to this Agreement. The Government further acknowledges that Regeneron holds the commercialization rights for all products developed under this Agreement in the U.S. and will be responsible for their registration with the FDA. This provision is subject to any applicable limitations on the Government's rights under Article VIII.B.a-b of the BARDA OTA.

7.4 REGULATORY RIGHTS

The Contractor agrees to the following:

a. Regulatory Data. Regeneron shall provide to the OTTR and OTAS copies of formal FDA submissions pertaining to the scope of the project, no later than 10 business days before submission to the FDA. For clarity, CMC Data included in such submissions shall be subject to Section 7.3.b.

b. Rights of Reference. Upon mutual agreement, Regeneron will grant to the Government a right of reference to any Regulatory Application submitted in support of this Project Agreement, solely for the purpose of the Government conducting a clinical trial with the drug product supplied under this Project Agreement under a protocol approved by Regeneron for performance

by the Government. In such a case, Regeneron agrees to provide a letter of cross-reference to the Government and file such letter with the appropriate FDA office. Nothing in this paragraph reduces the Government's data rights as articulated in other provisions of this award.

c. Clause 7.4.b. will survive the acquisition or merger of the Contractor by or with a third party. This clause will survive the expiration of this contract.

7.5 PREP Act Coverage. It is the intent of the Parties that the drug product provided pursuant to this Agreement be covered by the March 10, 2020 declaration under the Public Readiness and Emergency Preparedness Act (PREP Act), 42 U.S.C. § 247d-6d, 85 Fed Reg. 15,198 (March 17, 2020), or any amendments thereto that provides liability protection for such use. Based on an independent review by each of the Parties of the PREP Act Declaration issued by DHHS on March 10, 2020, pursuant to section 319F-3 of the Public Health Service Act (42 U.S.C. 247d-6d), and a related advisory opinion issued by the DHHS Office of General Counsel on April 14, 2020, the Parties believe that Regeneron is a covered person eligible for immunity under the PREP Act for activities related to medical countermeasures against COVID-19. To the extent DoD or BARDA is authorized to do so as an Authority Having Jurisdiction, the Government designates Regeneron as a covered person eligible for immunity under the PREP Act Declaration issued by DHHS on March 10, 2020, pursuant to section 319F-3 of the Public Health Service Act (42 U.S.C. 247d-6d), for activities related to medical countermeasures against COVID-19. The Government further warrants that the drug product provided pursuant to this Project Agreement will not be (a) sold to any entity nor will it be returned after acceptance under the terms of this contract or (b) distributed or used, or authorized for distribution or use, outside the United States or to the extent such activities are not protected from liability under an active PREP Act declaration.

7.6 Transparency. To the extent permitted under applicable laws, the Government will provide Regeneron in a timely manner copies of reports concerning this Project Agreement that are provided to other Government agencies or legislative or executive branches of the government.

8.0 SECURITY *AND SUPPLY CHAIN RESILIENCY*

The security classification level for this effort is UNCLASSIFIED.

9.0 MISCELLANEOUS REQUIREMENTS (SAFETY, ENVIRONMENTAL, ETC.)

N/A

10.0 GOVERNMENT FURNISHED PROPERTY/MATERIAL/INFORMATION

None

11.0 AGREEMENTS OFFICER'S REPRESENTATIVE (AOR) AND ALTERNATE AOR CONTACT INFORMATION

AOR

NAME:
EMAIL:
PHONE:
AGENCY NAME/DIVISION/SECTION: HHS/ASPR/BARDA

Alternate AOR
NAME:
EMAIL:
PHONE:
AGENCY NAME/DIVISION/SECTION: HHS/ASPR/BARDA

Requiring Activity:

US Department of Health & Human Services (HHS), Assistant Secretary for Preparedness and Response (ASPR), Biomedical Advanced Research and Development Authority (BARDA)

Definitions Appendix

Computer Software:
To perform and further this Project Agreement:
Computer programs that comprise a series of instructions, rules, routines, or statements, regardless of the media in which recorded, that allow or cause a computer to perform a specific operation or series of operations; and
Recorded information comprising source code listings, design details, algorithms, processes, flow charts, formulas, and related material that would enable the computer program to be produced, created, or compiled.
Does not include computer databases or computer software documentation.
Data: Means recorded information, regardless of form or the media on which it may be recorded. The term includes technical data and Computer Software. The term does not include information incidental to contract administration, such as financial, administrative, cost or pricing, or management information.
Field: The development of anti-pathogen assets to treat, diagnose or prevent emerging infectious diseases.
Government: The United States of America, as represented by the Department of Health & Human Services ("Government"), Office of the Assistant Secretary for Preparedness & Response ("ASPR"), Office of Biomedical Advanced Research and Development ("BARDA") (represented by Office of Acquisition Management, Contracts and Grants (AMCG)).
Government Purpose: Any activity in which the United States Government is a party, including cooperative agreements with international or multi-national defense organizations, or sales or transfers by the United States Government to foreign governments or international organizations. Government purposes include competitive procurement, but do not include the rights to use, modify, reproduce, release, perform, display, or disclose technical data for commercial purposes or authorize others to do so.

Government Purpose Rights: The rights by Government to—
1. Use, modify, reproduce, release, perform, display, or disclose technical data within the Government without restriction; and
2. Release or disclose technical data outside the Government and authorize persons to whom release or disclosure has been made to use, modify, reproduce, release, perform, display, or disclose that data for United States Government Purpose.

Invention: Any invention or discovery that is or may be patentable or otherwise protectable under Title 35 of the United States Code.
Limited Rights: The rights to use, modify, reproduce, perform, display, or disclose Data, in whole or in part, within the Government solely for research purposes for the Field. Government will ensure that disclosed information is safeguarded in accordance with the restrictions of this Agreement. The Government may not, without the prior written permission of Recipient, release or disclose the Data outside the Government, use the Data for competitive procurement or manufacture, release or disclose the data for commercial purposes, or authorize the Data to be used by another party. The Parties shall maintain the confidentiality of all Data subject to or designated as falling within Limited Rights.
Limited Rights Data: Data, other than Computer Software, that embody trade secrets or are commercial or financial and confidential or privileged, to the extent that such Data pertain to items, components, or processes developed at private expense, including minor modifications.
Made: The conception or first actual reduction to practice of the invention as defined in this Agreement.
Option: An option, entered into by bilateral agreement pursuant to a Statement of Work and budget, by which, for a specified time, the Government may elect to purchase additional supplies or services called for by the Agreement.
Other Transaction Agreement Officer ("OTAO"): Is the responsible Government official authorized to bind the Government by signing this Agreement and bilateral modifications.
Other Transaction Agreement Specialist ("OTAS"): Is a supporting official that assists and represents the OTAO. The OTAO is the only official who can bind the Government.
Other Transaction Agreement Technical Representative ("OTTR"): Is the primary Government official for all technical matters on the Agreement.
Practical Application: With respect to a Subject Invention, to manufacture, in the case of a composition or product; to practice, in the case of a process or method; or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the Subject Invention is capable of being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public for a regulatory approved product.
Subject Invention: Any Invention Made in the performance of work under this Agreement within the Field for which Recipient pursues a patent.
Sub-Recipient: Akin to a subcontractor. Any supplier, distributor, vendor, or firm that furnishes supplies or services to or for the Recipient, an Affiliate, or a Sub-Recipient. A Sub-Recipient differs from an Affiliate in that Sub-Recipients are not listed as an Affiliate in Attachment 3 and may be used to execute tasks under the SOW by Recipient or Affiliate.
Sub-Recipient Agreement: Any contract entered into by a Sub-Recipient to furnish supplies or services for performance of this Agreement. This term describes an agreement with a 1st-Tier Sub-Recipient, except as expressly noted in this Agreement.

SUBSIDIARIES OF REGENERON PHARMACEUTICALS, INC.

Name of Subsidiary*	State or Other Jurisdiction of Incorporation or Organization
Loop Road Holdings LLC	New York
Old Saw Mill Holdings LLC	New York
OSMR Holdings	Bermuda
OSMR International	Bermuda
Regeneron Assurance, Inc.	New York
Regeneron Atlantic Holdings	Bermuda
Regeneron Belgium BV	Belgium
Regeneron Canada Company	Canada
Regeneron Capital International B.V.	The Netherlands
Regeneron Genetics Center LLC	Delaware
Regeneron GmbH	Germany
Regeneron Healthcare Solutions, Inc.	New York
Regeneron International Holdings LLC	Delaware
Regeneron International Limited	Ireland
Regeneron Ireland Holdings Unlimited Company	Ireland
Regeneron Ireland Designated Activity Company	Ireland
Regeneron NL B.V.	The Netherlands
Regeneron Spain, S.L.U.	Spain
Regeneron UK Limited	United Kingdom
Rockwood Road Holdings LLC	New York

* Directly or indirectly wholly owned by Regeneron Pharmaceuticals, Inc.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-228352) and S-8 (Nos. 333-61132, 333-97375, 333-119257, 333-151941, 333-169569, 333-174863, 333-196799, 333-198794, 333-218669, and 333-239209) of Regeneron Pharmaceuticals, Inc., of our report dated February 8, 2021 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Florham Park, New Jersey
February 8, 2021

Exhibit 31.1

Certification of Principal Executive Officer Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Leonard S. Schleifer, certify that:

1. I have reviewed this annual report on Form 10-K of Regeneron Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, re ult of operation and ca h flow of the re i trant a of, and for, the period pre ented in thi report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5 The re i trant' other certifying officer and I have di clo ed, ba ed on our mo t recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 8, 2021

/s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Principal Financial Officer Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Robert E. Landry, certify that:

1. I have reviewed this annual report on Form 10-K of Regeneron Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 8, 2021

/s/ Robert E. Landry

Robert E. Landry
Executive Vice President, Finance and Chief Financial Officer
(Principal Financial Officer)

Certification of Principal Executive Officer and Principal Financial Officer Pursuant to
18 U.S.C. Section 1350,
As Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Principal Executive Officer of the Company, and Robert E. Landry, as Principal Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Leonard S. Schleifer
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)
February 8, 2021

/s/ Robert E. Landry
Robert E. Landry
Executive Vice President, Finance and Chief Financial Officer
(Principal Financial Officer)
February 8, 2021