

REGENERON

Press Release

Regeneron Reports Fourth Quarter and Full Year 2019 Financial and Operating Results

- Fourth quarter 2019 revenues increased 13% to \$2.17 billion versus fourth quarter 2018
- Fourth quarter EYLEA® U.S. net sales increased 13% to \$1.22 billion versus fourth quarter 2018 and full year 2019 EYLEA U.S. net sales increased 14% versus 2018
- Dupixent® global net sales⁽²⁾, which are recorded by Sanofi, increased 136% to \$752 million versus fourth quarter 2018 and increased to \$2.32 billion for full year 2019
- Fourth quarter 2019 GAAP diluted EPS was \$6.93 and fourth quarter non-GAAP diluted EPS⁽¹⁾ was \$7.50
- The Company and Sanofi announced intent to restructure antibody collaboration for Kevzara® and Praluent®

Tarrytown, New York (February 6, 2020) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the fourth quarter and full year 2019 and provided a business update.

"Regeneron had a very productive 2019 marked by strong commercial growth for our core franchises, significant pipeline and regulatory progress, and positive financial results," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "In 2020, we are focused on driving continued growth with EYLEA, Dupixent, and Libtayo and anticipate several new regulatory approvals and submissions across our portfolio. Our expanding pipeline of innovative and complementary immuno-oncology therapies continues to advance, and we feel confident that we are positioned to bring new breakthroughs to cancer patients and be a leader in this rapidly evolving field."

"We continue to work constructively with Sanofi to finalize our modified antibody agreement for Praluent and Kevzara, which we expect to be accretive in 2020," said Robert E. Landry, Executive Vice President, Finance and Chief Financial Officer of Regeneron. "We will provide financial guidance for full year 2020 by no later than the end of the first quarter."

Financial Highlights

	Three Months Ended December 31,			Year Ended December 31,		
	2019	2018	% Change	2019	2018	% Change
(\$ in millions, except per share data)						
Total revenues	\$ 2,170	\$ 1,928	13%	\$ 7,863	\$ 6,711	17%
GAAP net income	\$ 792	\$ 820	(3%)	\$ 2,116	\$ 2,444	(13%)
GAAP net income per share - diluted	\$ 6.93	\$ 7.15	(3%)	\$ 18.46	\$ 21.29	(13%)
Non-GAAP net income ⁽¹⁾	\$ 858	\$ 786	9%	\$ 2,827	\$ 2,622	8%
Non-GAAP net income per share - diluted ⁽¹⁾	\$ 7.50	\$ 6.84	10%	\$ 24.67	\$ 22.84	8%

Business Highlights

Key Pipeline Progress

Regeneron has 22 product candidates in clinical development, including five of the Company's U.S. Food and Drug Administration (FDA) approved products for which it is investigating additional indications. Updates from the clinical pipeline include:

EYLEA® (aflibercept) Injection

- In December 2019, the Company launched the EYLEA pre-filled syringe in the United States.

Dupixent® (dupilumab)

- In October 2019, the European Commission (EC) approved Dupixent in chronic rhinosinusitis with nasal polyposis (CRSwNP).
- The FDA accepted for priority review the supplemental Biologics License Application (sBLA) for children aged 6 to 11 years with moderate-to-severe atopic dermatitis, with a target action date of May 26, 2020. In addition, a Marketing Authorization Application (MAA) for children aged 6 to 11 years with moderate-to-severe atopic dermatitis was recently submitted in the European Union.
- A Phase 2/3 study in bullous pemphigoid and Phase 3 studies in prurigo nodularis and chronic spontaneous urticaria were initiated.

Libtayo® (cemiplimab)

- A Phase 2 neoadjuvant study in cutaneous squamous cell carcinoma (CSCC) was initiated.

REGN1979, a bispecific antibody targeting CD20 and CD3

- In December 2019, the Company reported updated results from the initial clinical trial in patients with non-Hodgkin lymphoma.
- The potentially pivotal Phase 2 study has been expanded to include patients with diffuse large B-cell lymphoma (DLBCL) and other non-Hodgkin lymphomas.

REGN5458, a bispecific antibody targeting BCMA and CD3

- In December 2019, the Company announced positive preliminary results from an initial clinical trial in patients with relapsed or refractory multiple myeloma.

Pozelimab, an antibody to C5

- In December 2019, the Company announced positive top-line results from a Phase 2 trial in paroxysmal nocturnal hemoglobinuria (PNH).

Garetosmab, an antibody to Activin A

- In January 2020, the Company announced encouraging results from a Phase 2 trial in fibrodysplasia ossificans progressiva (FOP).

REGN-EB3, a multi-antibody therapy to Ebola virus infection

- The *New England Journal of Medicine* published results from the randomized, controlled PALM trial showing that Regeneron's REGN-EB3 and another agent provided the highest overall survival rates among four investigational treatments for Ebola.

Business Development Update

- The Company and Sanofi announced their intent to restructure their antibody collaboration for Kevzara and Praluent and enter into a royalty-based arrangement. Under the proposed terms of the agreement, Sanofi is expected to gain sole global rights to Kevzara and sole rights to Praluent outside of the United States. Regeneron is expected to gain sole U.S. rights to Praluent. Under the proposed terms, each party will be solely responsible for funding development and commercialization expenses in their respective territories. The proposed agreement, which is expected to be finalized in the first quarter of 2020, will not impact the companies' existing collaboration relating to Dupixent and REGN3500.
- The Company entered into a research collaboration and option licensing agreement with Vyriad, Inc. to discover and develop new oncolytic (cancer-killing) virus-based treatments for various forms of cancer.

Select 2020 Milestones

Programs	Milestones
Dupixent	<ul style="list-style-type: none"> - FDA decision (target action date of May 26, 2020) on sBLA and EC decision for expanded atopic dermatitis indication in pediatric patients (6–11 years of age) - Report results from Phase 3 study for asthma in pediatric patients (6–11 years of age) - Report results from Phase 2 portion of Phase 2/3 study in eosinophilic esophagitis (EOE)
Libtayo	<ul style="list-style-type: none"> - Interim analysis of overall survival in Phase 3 non-small cell lung cancer (NSCLC) monotherapy study in patients with high PD-L1 expression - Report results from potentially pivotal Phase 2 study in basal cell carcinoma (BCC)
REGN1979 (CD20 and CD3 Antibody)	<ul style="list-style-type: none"> - Report updated results from initial study in certain B-cell malignancies - Continue to expand potentially pivotal Phase 2 study
REGN5458 (BCMA and CD3 Antibody)	<ul style="list-style-type: none"> - Report updated results from initial study in multiple myeloma
Evinacumab (ANGPTL3 Antibody)	<ul style="list-style-type: none"> - Submit BLA and MAA for homozygous familial hypercholesterolemia (HoFH)
Pozelimab (C5 Antibody)	<ul style="list-style-type: none"> - Initiate Phase 3 program in PNH - Initiate combination program with Alnylam's cemdisiran
Garetosmab (Activin A Antibody)	<ul style="list-style-type: none"> - Discuss regulatory submission for FOP with regulatory authorities
Fasimumab (NGF Antibody)	<ul style="list-style-type: none"> - Report results from Phase 3 studies in osteoarthritis pain of the knee or hip
REGN-EB3 (Multi-antibody therapy to Ebola)	<ul style="list-style-type: none"> - Complete rolling BLA submission for Ebola

Fourth Quarter and Full Year 2019 Financial Results

Total Revenues: Total revenues increased by 13% to \$2.170 billion in the fourth quarter of 2019, compared to \$1.928 billion in the fourth quarter of 2018. Full year 2019 total revenues increased 17% to \$7.863 billion, compared to \$6.711 billion for the full year 2018.

Net product sales were \$1.286 billion in the fourth quarter and \$4.834 billion for the full year 2019, compared to \$1.096 billion in the fourth quarter and \$4.106 billion for the full year 2018. EYLEA net product sales in the United States were \$1.222 billion in the fourth quarter and \$4.644 billion for the full year 2019, compared to \$1.079 billion in the fourth quarter and \$4.077 billion for the full year 2018. Overall distributor inventory levels for EYLEA in the United States remained within the Company's one-to-two-week targeted range.

Total revenues also include Sanofi and Bayer collaboration revenues⁽²⁾ of \$748 million in the fourth quarter and \$2.616 billion for the full year 2019, compared to \$729 million in the fourth quarter and \$2.188 billion for the full year 2018. Sanofi collaboration revenue in the fourth quarter and full year 2019 included the Company's share of profits from collaboration antibodies (Dupixent, Praluent, and Kevzara) of \$104 million and \$209 million, respectively, while Sanofi collaboration revenue in the fourth quarter and full year 2018 included the Company's share of losses from collaboration antibodies of \$(44) million and \$(227) million, respectively. The increase in the Company's share of profits from collaboration antibodies was primarily driven by higher Dupixent profits. Sanofi collaboration revenue in the fourth quarter of 2018 also included the recognition of a cumulative catch-up adjustment of \$149 million arising from a change in the estimate of the stage of completion of the collaborations' immunology programs primarily in connection with the Amended IO Discovery Agreement.

Refer to Table 4 for a summary of collaboration and other revenue.

Research and Development (R&D) Expenses: GAAP R&D expenses were \$683 million in the fourth quarter and \$3.037 billion for the full year 2019, compared to \$601 million in the fourth quarter and \$2.186 billion for the full year 2018. The higher R&D expenses in the fourth quarter of 2019 were principally due to additional costs incurred in connection with our earlier-stage pipeline and dupilumab, and higher headcount and headcount-related costs. The higher R&D expenses for the full year 2019 were principally due to a \$400 million up-front payment to Alnylam, additional costs incurred in connection with our earlier-stage pipeline, and higher headcount and headcount-related costs. R&D-related non-cash share-based compensation expense was \$72 million in the fourth quarter and \$250 million for the full year 2019, compared to \$68 million in the fourth quarter and \$229 million for the full year 2018.

Selling, General, and Administrative (SG&A) Expenses: GAAP SG&A expenses were \$587 million in the fourth quarter and \$1.835 billion for the full year 2019, compared to \$491 million in the fourth quarter and \$1.556 billion for the full year 2018. The higher SG&A expenses in the fourth quarter and full year 2019 were primarily due to higher headcount and headcount-related costs, an increase in commercialization-related expenses for Dupixent and EYLEA, additional accruals for loss contingencies associated with ongoing litigation, and higher contributions to independent not-for-profit patient assistance organizations. In addition, in the fourth quarter of 2019, the Company recorded a charge for restructuring-related costs, primarily related to employee separation costs, as the Company has eliminated certain commercialization activities and related headcount in connection with the proposed restructuring of the antibody agreement

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