IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH, Plaintiffs, v. MODERNA, INC. and MODERNATX, INC. Defendants.	)	C.A. No. 22-252 (MSG) **REDACTED - PUBLIC VERSION** Original filing date: January 25, 2024 Redacted filing date: February 2, 2024

BRIEF IN SUPPORT OF JOINT MOTION TO SEAL PORTIONS OF MODERNA'S OPPOSITION TO PLAINTIFFS' MOTION TO COMPEL AND EXHIBITS (D.I. 196)

SHAW KELLER LLP
John W. Shaw (#3362)
Karen E. Keller (#4489)
Nathan R. Hoeschen (#6232)
Emily S. DiBenedetto (#6779)
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com
nhoeschen@shawkeller.com
edibenedetto@shawkeller.com
Attorney for Plaintiffs

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
Jack B. Blumenfeld (#1014)
Brian P. Egan (#6227)
Travis J. Murray (#6882)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
began@morrisnichols.com
tmurray@morrisnichols.com

Attorneys for Defendants

OF COUNSEL:

David I. Berl
Adam D. Harber
Thomas S. Fletcher
Jessica Palmer Ryen
Shaun P. Mahaffy
Jihad J. Komis
Anthony H. Sheh
Matthew W. Lachman
Philip N. Haunschild
WILLIAMS & CONNOLLY LLP
680 Maine Avenue S.W.
Washington, DC 20024
(202) 434-5000

Attorneys for Plaintiff Genevant Sciences GmbH

Daralyn J. Durie
Adam R. Brausa
Eric C. Wiener
Annie A. Lee
Shaelyn K. Dawson
MORRISON & FOERSTER LLP
425 Market Street
San Francisco, CA 94105-2482
(415) 268-6080
Kira A. Davis
MORRISON & FOERSTER LLP
707 Wilshire Boulevard
Los Angeles, CA 90017-3543
(213) 892-5200

David N. Tan
MORRISON & FOERSTER LLP
2100 L Street, NW, Suite 900
Washington, DC 20037
(202) 887-1500

Attorneys for Plaintiff Arbutus Biopharma Corporation

OF COUNSEL:

Patricia A. Carson, Ph.D.
Jeanna M. Wacker, P.C.
Mark C. McLennan
Yan-Xin Li
Caitlin Dean
Nancy Kaye Horstman
Shaoyao Yu
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
(212) 446-4800

Alina Afinogenova
KIRKLAND & ELLIS LLP
200 Clarendon Street
Boston, MA 02116
(617) 385-7500

January 25, 2024

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I. INTRODUCTION

Pursuant to the Protective Order (D.I. 91) as modified by the Court's November 14, 2023 Order (D.I. 155), the parties' respectfully move this Court to seal their sensitive and confidential information and to grant leave to file partially redacted versions of Moderna's Opposition to Plaintiffs' Motion to Compel (D.I. 196) ("Moderna's Opposition") and Exhibits C, F, G, H, K, M, and N (collectively, the "Confidential Materials").[1] As explained in more detail below, the portions marked for redaction contain the parties' sensitive and confidential technical information, including confidential regulatory submissions and trade secrets.

In support of this motion, Moderna attaches as Exhibit 1 the Declaration of Peter Wojciechowski, CMC Knowledge Management Lead at ModernaTX, Inc. and Exhibit 2 the Declaration of Dan Staner, VP, & General Manager, Switzerland, Germany & Middle East at Moderna Switzerland GmbH who are knowledgeable about Moderna's confidential information that Moderna seeks to seal and are familiar with its sensitivity. In further support of this motion, Plaintiffs attach as Exhibit 3 the Declaration of Pete Zorn, President and Chief Legal Officer of Genevant Sciences, Inc. who is knowledgeable about Plaintiffs' confidential material that Plaintiffs seek to seal and is familiar with its sensitivity. The Confidential Materials contain the parties' highly confidential information, and the Court should maintain that material under seal in order to prevent serious and real harm to the parties. Release of the parties' highly confidential information to the public and the parties' competitors would create a clearly defined and serious injury to the parties, as discussed in detail below.

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[1] Plaintiffs' proposed redactions are in teal highlighting and Defendants' proposed redactions are in green highlighting. Yellow highlighting was used for emphasis by the parties in the originally filed exhibits and does not indicate proposed redactions.

II. LEGAL STANDARD

Third Circuit common law presumes a public right of access to judicial records; however it also protects business and financial information when access would cause economic harm, including competitive harm. *In re Avandia Mktg., Sales Pracs. & Prod. Liab. Litig.*, 924 F.3d 662, 672 (3d Cir. 2019). "Although the common law right to public access is a recognized and venerated principle, courts have also recognized the accompanying principle that the right is not absolute." *In re Cendant Corp.*, 260 F.3d 183, 194 (3d Cir. 2001) (citations and quotations omitted); *see also Littlejohn v. Bic Corp.*, 851 F.2d 673, 678 (3d Cir. 1988) ("Despite the presumption, courts may deny access to judicial records, for example, where they are sources of business information that might harm a litigant's competitive standing.").

This presumption is overcome where a movant shows "that the interest in secrecy outweighs the presumption." *Avandia Mktg.*, 924 F.3d at 672 (quoting *Bank of Am. Nat'l Tr. & Sav. Ass'n v. Hotel Rittenhouse Assocs.*, 800 F.2d 339, 344 (3d Cir. 1986)). This showing may be made by demonstrating that disclosure will work a clearly defined and serious injury to the movant and that the material is the kind of information that courts will protect. *See Avandia Mktg.*, 924 F.3d at 672 (citing *Miller v. Ind. Hosp.*, 16 F.3d 549, 551 (3d Cir. 1994)). The Court will apply a "good cause" standard justifying sealing or redacting judicial records, requiring a "balancing process, in which courts weigh the harm of disclosing information against the importance of disclosure to the public." *Mosaid Techs. Inc. v. LSI Corp.*, 878 F. Supp. 2d 503, 507–08 (D. Del. 2012) (citing *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 787 (3d Cir. 1994)).

III. ARGUMENT

A. Moderna's Confidential Materials

Moderna seeks to file redacted versions of Moderna's Opposition and Exhibits C, G, and H thereto (collectively, "Moderna's Confidential Materials").

Good cause exists here to seal Moderna's Confidential Materials because they contain Moderna's highly confidential technical and business information. Disclosure of such information would cause real and serious competitive harm to the parties, and the information does not need to be disclosed to the public to understand the filings at issue.

Although the public's presumptive common law right of access to judicial records attaches to materials filed in connection with a pretrial motion of a non-discovery nature, this right is "not absolute" and may be overcome by a showing that the material sought to be sealed "is the kind of information that courts will protect and will work a clearly defined and serious injury to the party seeking closure." *Avandia Mktg.*, 924 F.3d at 673 (citation omitted). Here, Moderna's Confidential Materials are all the types of limited information of the kind that courts in the Third Circuit have recognized as protectable, namely highly sensitive and confidential technical information regarding Moderna's proprietary and trade secret manufacturing methods for its COVID-19 Vaccine, including steps in the manufacturing process and parameters for those steps.

The harms caused by revealing Moderna's confidential information are discussed below, and further in the attached declarations of Peter Wojciechowski (Exhibit 1), CMC Knowledge Management Lead at ModernaTX, Inc., and Dan Staner (Exhibit 2), VP, & General Manager, Switzerland, Germany & Middle East at Moderna Switzerland GmbH, who are familiar with this information and its sensitivity. As Mr. Wojciechowski explains, there is significant competition between established vaccine suppliers, including suppliers with mRNA-based vaccines, like Moderna, and any information about one of these competitors, even seemingly minor information, may prove competitively advantageous. Ex. 1, ¶ 7.

Moderna seeks only to partially seal Moderna's Confidential Materials at issue in this motion. As described briefly below, and further explained in the Declaration of Peter

Wojciechowski (Exhibit 1) and the Declaration of Dan Staner (Exhibit 2), Moderna's Confidential Materials contain Moderna's and third parties' confidential information. Moderna's Confidential Materials contain highly confidential and sensitive information regarding the composition of Moderna's COVID-19 Vaccine (known as mRNA-1273 or "SpikeVax"), Moderna's proprietary and trade secret manufacturing methods for its COVID-19 Vaccine including steps in the manufacturing process and parameters for those steps, and commercially sensitive third-party material contained in foreign customer contracts. Ex. 1, ¶ 6; Ex. 2, ¶ 5. SpikeVax is comprised of messenger RNA (mRNA) which is delivered using lipid nanoparticles (LNPs). Ex. 1, ¶ 3. Moderna's proprietary LNP is comprised of four lipid components including SM-102, cholesterol, phospholipid, and PEGDMG-2000. *Id.* With respect to Moderna's formulation, Moderna considers its precise formulation, including the specific quantities of ingredients, a trade secret, which is not public knowledge. *Id.*, ¶ 8. With respect to Moderna's manufacturing process for SpikeVax, Moderna considers its process-as-a-whole a trade secret, including the steps in the process, the records of each step, and the parameters or specification for each step (such as timing, sequence, amount and kind of raw materials, temperatures, measurements, equipment used etc.). *Id.*, ¶ 9. Moderna has not publicly disclosed its proprietary manufacturing process. *Id.* With respect to the information contained in Moderna's contracts with third parties, Moderna owes a duty of confidentiality to these third parties which would require notice to each third party prior to public disclosure. Ex. 2, ¶ 7. Publicly revealing terms of the contracts with third parties could harm Moderna's relationship with these third parties. *Id.*

Specifically, Moderna has not publicly disclosed information within Moderna's Opposition and Exhibits C, G, and H which refer to, quote, summarize, or otherwise disclose Moderna's sensitive and confidential technical information. Specifically, the information on the following

pages of Moderna's Opposition and Exhibits disclose specific information concerning the composition of Moderna's COVID-19 Vaccine, Moderna's proprietary and trade secret manufacturing methods for its COVID-19 Vaccine including steps in the manufacturing process and parameters for those steps, and commercially sensitive third-party material contained in foreign customer contracts:

- Moderna's Opposition at page 2, lines 27-30;
- Exhibit C at page 2, line 37;
- Exhibit G at page 3, lines 11, 18-19; page 4, lines 1-2; page 6, lines 17-20;
- Exhibit H at page 1, lines 1-35; page 2, lines 1-53.

Because of the highly competitive nature of the vaccine supplier market, Moderna has spent significant effort and resources to develop these manufacturing methods and formulations, and the release of such information to the public, including Moderna's competitors, would harm Moderna. Ex. 1, ¶ 7. Because there are so few competitors in the vaccine supplier market, the market is highly competitive, and any information about one of the competitors, even seemingly minor information, may prove competitively advantageous. *Id.*; Ex. 2, ¶ 6. Additionally, there are companies considering entering the vaccine market and companies developing mRNA-based vaccines and therapeutics for other diseases or developing lipid nanoparticles for mRNA-based products. Ex. 1, ¶ 7; Ex. 2, ¶ 6.

Moderna's Confidential Materials also include highly confidential business information regarding Moderna's COVID-19 Vaccine. Ex. 1, ¶ 6; Ex. 2, ¶ 5. If the confidential information were made public, Moderna's competitors would be able to potentially replicate Moderna's products, features within Moderna's products, and methods of making mRNA-LNP products, or make decisions about where, when, and how to offer directly competitive goods with full knowledge of Moderna's technology. Ex. 1, ¶ 11. Moderna's competitors would gain a significant

advantage in creating their own business strategies, which would put Moderna at a significant competitive disadvantage, causing it real and serious harm. *Id.* Moderna's competitors may also seek patent claims to cover Moderna's technology. *Id.*

Moderna has always taken extensive measures to maintain the confidentiality of its technical information. *Id.*, ¶ 5; Ex. 2, ¶ 4. Moderna has been extremely concerned about the protection of its confidential information during this litigation and has been very careful to always protect this information. Ex. 1, ¶ 5; Ex. 2, ¶ 4. Moderna has invested significant resources to develop this information as well, Ex. 1, ¶ 7, and this information is of the type that courts have recognized as protectable. *See, e.g.*, *Nitto Denko Corp. v. Hutchinson Tech. Inc.*, No. CV 16-3595 (CCC/MF), 2017 WL 2782639, at *2 (D.N.J. Mar. 3, 2017) (granting motion to seal "confidential technical information" where such information "was not intended to be seen by competitors . . . for review and potential use against the parties" and parties were in "highly competitive [] industry"); *Guardant Health, Inc. v. Foundation Med., Inc.*, C.A. Nos. 17-1616-LPS-CJB, D.I. 447 (D. Del. June 16, 2020) (granting motion to redact confidential information concerning defendant's confidential technical information).

Disclosure of Moderna's confidential information regarding the technical details of Moderna's precise formulation, the proprietary manufacturing process for SpikeVax, or commercially sensitive third-party material contained in foreign customer contracts would "work a clearly defined and serious injury" to Moderna, as such disclosure would provide Moderna's competitors, customers, and potential licensors or licensees with otherwise confidential information regarding Moderna's products and strategies, as well as a competitive advantage in both the vaccine supplier market and in negotiations with Moderna. *See Pansy*, 23 F.3d at 786. Moreover, because this "case involves private litigants" and their confidential information, there

is "little legitimate public interest" in the proposed redactions. *Id.* at 788. Under such circumstances, Moderna's interest in maintaining the confidentiality of the proposed redacted information outweighs any countervailing public interest. *See id.* ("[I]f a case involves private litigants, and concerns matters of little legitimate public interest, that should be a factor weighing in favor of granting or maintaining an order of confidentiality."); *Leucadia, Inc. v. Applied Extrusion Tech., Inc.*, 998 F.2d 157, 166 (3d Cir. 1993) ("Documents containing trade secrets or other confidential business information may be protected from disclosure" and explaining that the court has "framed the inquiry as whether the need for secrecy outweighs the presumption of access that normally attaches to such documents"); *Nixon v. Warner Commc'ns, Inc.*, 435 U.S. 589, 598 (1978) ("[C]ourts have refused to permit their files to serve as . . . sources of business information that might harm a litigant's competitive standing.").

As explained above, Moderna's Confidential Materials contain technical details regarding Moderna's proprietary LNP formulation in SpikeVax, the related proprietary manufacturing process, and commercially sensitive third-party material contained in foreign customer contracts. Moderna's proposed redactions to Moderna's Opposition and Exhibits C, G, and H thereto only redact the specific confidential material at issue, leaving the remainder unredacted. These proposed redactions are narrow such that the public's ability to understand the arguments is not impaired any less than necessary to prevent the release of Moderna's most sensitive technical information to its competitors, preventing clear competitive harm. Moderna's proposed redactions are narrow in scope and refer only to Moderna's confidential, sensitive technical or business information to prevent the serious harm to Moderna which would be caused by its public release as outlined in Mr. Wojciechowski's and Mr. Staner's declarations.

B. Plaintiffs' Confidential Materials

Plaintiffs seek to file redacted versions of Moderna's Opposition and Exhibits F, K, M, and N thereto (collectively, "Plaintiffs' Confidential Materials").

Good cause exists here to seal Plaintiffs' Confidential Materials because they contain Plaintiffs' highly confidential business information, and the confidential information of third parties. Disclosure of such information would cause real and serious competitive harm to Plaintiffs and the information does not need to be disclosed to the public to understand the filings at issue.

Plaintiffs' Confidential Materials are the type of information that courts in the Third Circuit have recognized as protectable, namely highly sensitive and confidential business information regarding Plaintiffs' license and business agreements with third parties, and details about Plaintiffs' ongoing work to commercialize these LNPs and secure appropriate intellectual property protection for their LNP technology. *Avandia Mktg.*, 924 F.3d at 673; *Kaleo, Inc. v. Adamis Pharms. Corp.*, No. CR 19-917-RGA, 2019 WL 11680196, at *2 (D. Del. July 16, 2019) (granting motion to seal "details of, discussion of, and/or reference surrounding licensing negotiations . . . which refer to timing of the discussions that led up to the execution of the agreement and the breadth of subject matter to be included in the license," and finding "this information provides subsequent licensees insight into the factors beyond the financial terms that Adamis considers during licensing"); *id.* (good cause to seal information that "provides insight on Adamis' legal and business strategy"); *Techfields Pharma Co. v. Covance Inc.*, No. 3:16-CV-1148-MAS-LHG, 2019 WL 2478109, at *2 (D.N.J. June 13, 2019) (granting motion to seal discussion of contracts that are subject to confidential negotiations, where disclosure would put party at disadvantage in future negotiations); *United States v. Dentsply Int'l, Inc.*, 187 F.R.D. 152, 159 (D. Del. 1999) (shielding a nonparty competitors' information from disclosure); *Pansy*, 23 F.3d at 786.

The harms caused by revealing Plaintiffs' confidential information are discussed below, and further in the attached declaration of Pete Zorn (Exhibit 3), President and Chief Legal Officer of Genevant Sciences, Inc., who is familiar with this information and its sensitivity. As Mr. Zorn explains, there is significant competition in connection with the research, development, and sale of products related to Plaintiffs' LNP technology, as well as the development and maintenance of appropriate intellectual property protection for Plaintiffs' LNP technology. Ex. 3, ¶¶ 13–14. Any information about one of the competitors in Plaintiffs' industry, even seemingly minor information, may prove competitively advantageous. *Id.* Further, Plaintiffs continue to work with third parties regarding LNP Technology, and the disclosure of these third parties' information would hinder Plaintiffs' ability to enter into further confidential third-party business relationships.

As described briefly below, and further explained in the Declaration of Mr. Zorn, Plaintiffs consider as confidential information the details of their commercial arrangements with other parties, the details of their negotiations and license agreements with collaborators regarding LNP technology, and their patent prosecution efforts. Ex. 3, ¶¶ 7, 10, 12. Plaintiffs' development and maintenance of their commercial relationships regarding the development of LNP work is ongoing. Moderna's Opposition and the exhibits at issue refer to a communication between Plaintiffs and a third-party collaborator with which Genevant entered into a license agreement; the details of Plaintiffs' commercial agreements with Roivant Sciences, Inc.; and a communication with Plaintiffs' counsel regarding the prosecution of a certain patent. Plaintiffs have not publicly disclosed the information within Moderna's Opposition and Exhibits F, K, M, and N, thereto which refer to, summarize, or otherwise disclose Plaintiffs' confidential communications and agreements with third parties and Plaintiffs' counsel for patent prosecution. Specifically, the information on the following pages of Moderna's Opposition and Exhibits disclose information concerning

Plaintiffs' confidential agreements, and details about Plaintiffs' ongoing work to develop, commercialize, and secure appropriate intellectual property protection for their LNP technology:

- Moderna's Opposition at Page 3, Footnote 4, lines 3–4
- Exhibit F, at Page 5, Lines 2–3
- Exhibit K, at Page 5, Lines 5–9
- Exhibit M, at Page 2, Lines 4–7, 16, 24–25
- Exhibit N, at Page 2, Lines 3–6, 9–10, 14, 17–20, 23–33, Page 3, Lines 1, 5–6, 8–44, Page 4, Lines 1, 3–11

Because of the highly competitive nature in connection with the research, development, and sale of products related to Plaintiffs' LNP technology, Plaintiffs have spent significant effort and resources to develop their third-party relationships and collaborations, and to secure appropriate intellectual property protection for Plaintiffs' LNP technology. Plaintiffs have spent significant resources to pursue the appropriate intellectual property to protect their inventions regarding LNP technology, and to build collaborations and relationships with other third parties, and the release of confidential information regarding these efforts to the public, including Plaintiffs' competitors, would significantly harm Plaintiffs. Ex. 3, ¶¶ 13–14. Any information about one of these competitors, even seemingly minor information, may prove competitively advantageous. Ex. 3, ¶ 14. If Plaintiffs' Confidential Materials were made public, Plaintiffs would be competitively disadvantaged in securing appropriate intellectual property protection, and entering into appropriate commercial relationships with other third parties.

Plaintiffs have always taken extensive measures to maintain the confidentiality of third-party information, as well as their confidential business arrangements, and their efforts to secure appropriate intellectual property protection. Ex. 3, ¶ 12. Plaintiffs have invested significant resources to develop this information as well, Ex. 3, ¶¶ 10–11, 13, and this information is of the

type that courts have recognized as protectable. *E.g., Kaleo, Inc.*, 2019 WL 11680196, at *2 (finding good cause to seal information that "provides insight on Adamis' legal and business strategy"); *Valeant Pharm. Int'l, Inc. v. Mylan Pharm., Inc.*, Case No. 15-8180, D.I. 320 (D.N.J. May 22, 2018).

Disclosure of Plaintiffs' confidential information regarding their business arrangements and their efforts to secure appropriate intellectual property protection, as well as confidential third-party information, would "work a clearly defined and serious injury" to Plaintiffs, as such disclosure would provide Plaintiffs' competitors, customers, and potential licensors or licensees with otherwise confidential information regarding Plaintiffs' strategies, as well as a competitive advantage in both the market and in negotiations with Plaintiffs. *See Pansy*, 23 F.3d at 786; *Nitto Denko*, 2017 WL 2782639, at *2. Furthermore, if the confidential information of third parties that Plaintiffs' obtained pursuant to confidentiality agreements were disclosed, then Plaintiffs would be harmed in their ability to ensure potential third-party collaborators that the disclosure of third-party information to Plaintiffs will remain in confidence. *See* Ex. 3, ¶¶ 5, 11, 13.

And because this "case involves private litigants" and their confidential information, there is "little legitimate public interest" in the proposed redactions. *Pansy*, 23 F.3d at 788. Under such circumstances, Plaintiffs' interest in maintaining the confidentiality of the proposed redacted information outweighs any countervailing public interest. *See id.*

As explained above, Plaintiffs' Confidential Materials contain technical details regarding the research, development, and sale of products related to Plaintiffs' LNP technology. Plaintiffs proposed redactions to Moderna's Opposition and Exhibits F, K, M, and N remove the specific confidential material at issue, leaving non-confidential information unredacted. These proposed redactions are narrow, such that the public's ability to understand Moderna's Opposition is not

impaired any less than necessary to prevent the release of Plaintiffs' sensitive business and commercial information to its competitors, preventing clear competitive harm. Plaintiffs' proposed redactions are narrow in scope and refer only to Plaintiffs' confidential, sensitive technical or business information to prevent the serious harm to Plaintiffs which would be caused by its public release as outlined in Mr. Zorn's Declaration.

Exhibit F is a confidential letter from Genevant's counsel to counsel for Moderna that includes information about the documents that Genevant is producing in this case, the disclosure of which could potentially interfere with Genevant's business and collaborations with third parties. Ex. 3. ¶ 5. Exhibit K includes Genevant's response to Moderna's interrogatory relating to the specifics of Genevant and Arbutus's commercial and business relationships with Roivant Sciences Ltd., specifically regarding whether Roivant is entitled to receive Litigation Proceeds in connection with this litigation. Genevant's response discloses specific information regarding the commercial agreements that have been entered into between Roivant and Plaintiffs. Ex. 3, ¶ 6. Exhibit M is a confidential communication between individuals at Genevant, Arbutus, and patent counsel who have provided patent prosecution services, that discloses the specific individuals who remain apprised of and assist with the efforts to appropriately secure intellectual property protection for Plaintiffs' inventions. Ex. 3. ¶ 7. Exhibit N is an email chain that includes details concerning the confidential negotiations of a licensing agreement that was entered into between Genevant and a third party, for which the negotiations were conducted pursuant to confidentiality agreements. Ex. 3. ¶ 8. In addition to disclosing the third party's confidential information, Exhibit N discloses the specific individuals who have participated in Plaintiffs' ongoing efforts to license Plaintiffs' LNP technology, and to engage in commercial collaborations. *Id.* Sealing portions of Exhibits F, K, M, and N does not impair the public's ability to understand Moderna's Opposition

any more than necessary to prevent the release of Plaintiffs' and third parties' confidential business and commercial information, preventing clear competitive harm.

IV. CONCLUSION

For the foregoing reasons, the parties jointly request the Court grant this Motion to Seal with respect to the parties' highly confidential information.

SHAW KELLER LLP

/s/ Nathan R. Hoeschen

John W. Shaw (#3362)
Karen E. Keller (#4489)
Nathan R. Hoeschen (#6232)
Emily S. DiBenedetto (#6779)
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com
nhoeschen@shawkeller.com
edibenedetto@shawkeller.com
Attorney for Plaintiffs

OF COUNSEL:

David I. Berl
Adam D. Harber
Thomas S. Fletcher
Jessica Palmer Ryen
Shaun P. Mahaffy
Jihad J. Komis
Anthony H. Sheh
Matthew W. Lachman
Philip N. Haunschild
WILLIAMS & CONNOLLY LLP
680 Maine Avenue S.W.
Washington, DC 20024
(202) 434-5000

Attorneys for Plaintiff Genevant Sciences GmbH

Daralyn J. Durie
Adam R. Brausa
Eric C. Wiener
Annie A. Lee
Shaelyn K. Dawson
MORRISON & FOERSTER LLP
425 Market Street
San Francisco, CA 94105-2482

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Travis J. Murray

Jack B. Blumenfeld (#1014)
Brian P. Egan (#6227)
Travis J. Murray (#6882)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
began@morrisnichols.com
tmurray@morrisnichols.com

Attorneys for Defendants

OF COUNSEL:

Patricia A. Carson, Ph.D.
Jeanna M. Wacker, P.C.
Mark C. McLennan
Yan-Xin Li
Caitlin Dean
Nancy Kaye Horstman
Shaoyao Yu
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
(212) 446-4800

Alina Afinogenova
KIRKLAND & ELLIS LLP
200 Clarendon Street
Boston, MA 02116
(617) 385-7500

(415) 268-6080

Kira A. Davis
MORRISON & FOERSTER LLP
707 Wilshire Boulevard
Los Angeles, CA 90017-3543
(213) 892-5200

David N. Tan
MORRISON & FOERSTER LLP
2100 L Street, NW, Suite 900
Washington, DC 20037
(202) 887-1500

Attorneys for Plaintiff Arbutus Biopharma Corporation

January 25, 2024

CERTIFICATE OF SERVICE

I hereby certify that on January 25, 2024, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on January 25, 2024, upon the following in the manner indicated:

John W. Shaw, Esquire — *VIA ELECTRONIC MAIL*
Karen E. Keller, Esquire
Nathan R. Hoeschen, Esquire
Emily S. DiBenedetto, Esquire
SHAW KELLER LLP
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
Attorneys for Plaintiffs Arbutus Biopharma Corporation and Genevant Sciences GmbH

Daralyn J. Durie, Esquire — *VIA ELECTRONIC MAIL*
Adam R. Brausa, Esquire
Eric C. Wiener, Esquire
Annie A. Lee, Esquire
Shaelyn K. Dawson, Esquire
MORRISON & FOERSTER LLP
425 Market Street
San Francisco, CA 94105-2482
Attorneys for Plaintiff Arbutus Biopharma Corporation

Kira A. Davis, Esquire — *VIA ELECTRONIC MAIL*
MORRISON & FOERSTER LLP
707 Wilshire Boulevard
Los Angeles, CA 90017-3543
Attorneys for Plaintiff Arbutus Biopharma Corporation

David N. Tan, Esquire
MORRISON & FOERSTER LLP
2100 L Street, NW, Suite 900
Washington, DC 20037
Attorneys for Plaintiff Arbutus Biopharma Corporation

VIA ELECTRONIC MAIL

David I. Berl, Esquire
Adam D. Harber, Esquire
Thomas S. Fletcher, Esquire
Jessica Palmer Ryen, Esquire
Shaun P. Mahaffy, Esquire
Anthony H. Sheh, Esquire
Philip N. Haunschild, Esquire
Jihad J. Komis, Esquire
Matthew W. Lachman, Esquire
WILLIAMS & CONNOLLY LLP
680 Maine Avenue S.W.
Washington, DC 20024
Attorneys for Plaintiff Genevant Sciences GmbH

VIA ELECTRONIC MAIL

/s/ Travis J. Murray

Travis J. Murray (#6882)