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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

JANSSEN PHARMACEUTICA NV,
JANSSEN BIOTECH, INC., and
ASTEX THERAPEUTICS LTD.,

Plaintiffs,

v.

NATCO PHARMA LTD.,

Defendant.

Civil Action No. 2:23-cv-03959-BRM-JRA

Hon. José R. Almonte

[PROPOSED] DISCOVERY CONFIDENTIALITY ORDER

The undersigned counsel for Plaintiffs Janssen Pharmaceutica NV, Janssen Biotech, Inc, and Astex Therapeutics Ltd. (together, “**Plaintiffs**”) and Defendant Natco Pharma Ltd. (“**Natco**”) (collectively, the “**Parties**” and each, a “**Party**”) in the above-captioned action, Civil Action No. 2:23-cv-03959-BRM-JRA in the United States District Court for the District of New Jersey (“**this Action**”) agree that the Parties will be required to produce or disclose, and non-parties may be required to produce or disclose, certain information and documents that are subject to confidentiality limitations on disclosure under applicable laws and regulations and applicable privacy rights. Such documents, described in more detail below, include information that may be a trade secret or other confidential research, development, manufacturing, regulatory, financial, or commercial information or that is of a private or personal nature. Disclosure of such information without reasonable restriction on the use of the information may cause harm, damage, loss, embarrassment, or disadvantage to the Producing Party or non-party.

Accordingly, the Parties desire entry of an order, pursuant to Federal Rule of Civil Procedure 26(c) and Local Civil Rule 5.3, and other applicable laws and rules, that will facilitate the prompt resolution of concerns or disputes over confidentiality, that will adequately protect confidential material and ensure that protection is afforded only to material so entitled, and that will address any unintentional production of documents or information protected from disclosure by the attorney-client privilege, work-product immunity, common interest protection, or other applicable privilege or immunity.

Therefore, the Parties hereby STIPULATE, and the Court, for good cause shown and after having an opportunity to discuss this Confidentiality Order with the Parties, hereby ORDERS that the following procedures shall be followed in this Action to facilitate the orderly and efficient discovery of relevant information while minimizing the potential for unauthorized disclosure or use of confidential or proprietary information and documents.

I. Purpose.

The Parties recognize that preparation for any trial of this Action may require the discovery of certain information that a Producing Party reasonably believes should be subject to confidential treatment under a protective order. The designation of a document, material, or information (whether written, graphic, or electronic) as being subject to the terms and conditions of this Discovery Confidentiality Order (“**Confidentiality Order**”), is intended to facilitate prompt discovery and the preparation for trial of this Action.

II. Scope.

- A. This Confidentiality Order shall govern all hardcopy and electronic materials, the Information contained therein, and all other Information including all copies, excerpts, summaries, or compilations thereof, whether revealed in a Document, deposition, other Testimony, discovery response, or otherwise, that any Party or non-party to this proceeding produces to any other Party and designates as Confidential Material under this Confidentiality Order.
- B. This Confidentiality Order is binding upon all Parties and their counsel in this Action, upon all signatories to the Endorsement of Confidentiality Order attached

hereto as Exhibit A (deemed to be part of this Order), upon (as applicable) their respective corporate parents, subsidiaries, and affiliates, including their successors, and their respective attorneys, principals, experts, consultants, representatives, agents, directors, officers, employees, and others as set forth in this Confidentiality Order, and upon all other persons or entities authorized under this Order or any other Order of this Court to receive or view Confidential Material.

- C. If additional parties are added other than parents, subsidiaries or affiliates of current Parties to this litigation, their ability to receive a Document or Information protected by this Confidentiality Order will be subject to their being bound, by agreement or Court Order, to this Confidentiality Order.
- D. Third parties who are obligated to produce Confidential Material in this Action and who so elect may avail themselves of, and agree to be bound by, the terms and conditions of this Confidentiality Order and thereby become a Producing Party and/or Designating Party for purposes of this Confidentiality Order.
- E. The entry of this Confidentiality Order does not preclude any Party from seeking a further order of this Court, including modification of this Confidentiality Order, or from objecting to discovery that the Party believes to be improper. This Confidentiality Order may be modified, and any matter related to it may be resolved, by written stipulation of the Parties without further order of the Court, subject to the requirements of Local Civil Rule 5.3. This Confidentiality Order supersedes any agreements between the Parties regarding the confidentiality of particular information entered into before the date of this Confidentiality Order.
- F. Nothing herein shall be construed as an admission or concession by any Party that any designated Confidential Material, or any Document or Information derived from Confidential Material, constitutes material, relevant, or admissible evidence in this matter.

III. **Definitions.**

In this Confidentiality Order, the terms set forth below shall have the following meanings:

- A. **“Confidential Material”** means any non-public Document (electronic or hard copy), Testimony, or Information that a Producing Party reasonably believes to be entitled to confidential treatment and that the Producing Party / Designating Party designates as such in accordance with the provisions of this Confidentiality Order.
 - 1. Confidential Material includes, but is not limited to:
 - a. Personal identifying information, financial information, personal medical/insurance information, and any other information that the Designating Party reasonably believes to be subject to protection from disclosure by a natural person’s right of privacy under

applicable privacy laws or regulations or by other federal, state or foreign data protection laws or privacy obligations, including without limitation the Health Insurance Portability and Accountability Act and the regulations thereunder, 45 C.F.R. Part 160 and Subparts A and E of Part 164 (medical information);

- b. Trade secrets (as defined in the Uniform Trade Secrets Act);
- c. Documents, Information, or Testimony containing or constituting confidential research and development, marketing, training, business, commercial, financial, technical, or proprietary information or data, manufacturing processes, product specifications, engineering information and testing, distribution processes, sensitive health or medical information, or other proprietary or confidential business information of commercial value or that, if disclosed, could result in competitive, commercial, or business harm;
- d. Any other information the Designating Party believes in good faith to be entitled to protection under Federal Rule of Civil Procedure 26(c)(1)(G) or Local Civil Rule 5.3; and
- e. All material, information, copies, data, extracts, compilations, summaries, and reports obtained, derived, or generated from Confidential Material, to the extent the same are not publicly available or otherwise subject to the exclusions herein.

2. Specifically excluded from the definition of Confidential Material are:

- a. Any Documents, Testimony, or Information that have been designated as “not confidential” by order of any court or disclosed publicly by any court;
- b. Any Documents, Testimony, or Information obtained legitimately from an independent source and to which no obligation of confidentiality was attached.

B. **“Counsel”** means Outside Counsel and in-house counsel, as well as their respective employees and support staff.

C. **“Court”** means the Honorable Judges currently assigned to this Action or any other judge to which this Action may be assigned, including Court staff.

D. **“Designating Party”** means the Party or non-party that designates Documents, Testimony, or Information as Confidential Material.

- E. **“Disclose,” “Disclosed” or “Disclosure”** means to reveal, divulge, give, or make available Information, Documents, Testimony, or any part thereof, or any Information contained therein.
- F. **“Document” or “Documents”** shall have the meaning set out in Federal Rule of Civil Procedure 34(a) and Local Civil Rule 5.2(1)(a) and, for purposes of this Confidentiality Order, shall include electronically stored information.
- G. **“Information”** means the contents of Documents or Testimony or discovery responses, as well as any matter derived therefrom or based thereon.
- H. **“Outside Counsel”** means attorneys who are not employees of a Party to this Action but have been retained to represent or advise a Party to this Action and have appeared in this Action on behalf of that Party, or persons or agents affiliated with or under contract with, a law firm which has appeared on behalf of that Party.
- I. **“Party”** means any party to this Action.
- J. **“Producing Party”** means the Party or non-party Disclosing Documents, Testimony, or Information in this Action.
- K. **“Receiving Party”** means the Party or non-party receiving Documents, Testimony, or Information that has been designated as Confidential Material pursuant to the provisions of this Confidentiality Order.
- L. **“Testimony”** means all depositions, declarations, sworn statements, or other pre-trial testimony taken or used in this Action.

IV. **Designation of Confidential Material.**

- A. **Documents Produced in TIFF format.** With respect to any Document produced in TIFF format, a Designating Party may designate the Document as Confidential Material by placing a stamp or marking on each page of the Document stating the following: **CONFIDENTIAL**. Such markings shall not obscure, alter, or interfere with the legibility of the original document.
 - 1. All copies, duplicates, extracts, summaries, or descriptions (hereinafter referred to collectively as “copies”) of Confidential Material produced in TIFF format shall be marked, if appropriate, with the same confidential stamp or marking as contained on the TIFF as originally produced.
- B. **Documents Produced in Native Format.** With respect to any Document produced in native format (**“Native-Format Document”**), a Designating Party may designate the Document as Confidential Material by renaming the Document to include, at the end of the file name and prior to the file extension, the following: **CONFIDENTIAL**. A corresponding stamp or marking must also be placed upon any associated slip sheet.

1. Native-Format Documents may have to be copied or duplicated in native format for use either within or outside of a litigation-support review application. Any such copy or duplicate shall retain the full file name as originally produced and shall be subject to the disclosure restrictions of this Confidentiality Order.
2. All other copies or duplicates of Native-Format Documents, and all extracts, summaries, or descriptions of Native-Format Documents shall, to the extent reasonably practicable and appropriate, contain a stamp or marking on each page of the Document stating the following:
CONFIDENTIAL. Such markings shall not obscure, alter, or interfere with the legibility of the original document.

C. Deposition Transcripts and Exhibits.

1. During depositions, Confidential Material (whether designated before or during the deposition) may be used or marked as exhibits, but shall remain subject to this Confidentiality Order and may not be shown to the witness unless such witness is a Qualified Person as described below.
2. If deposition Testimony or exhibits contain or refer to Confidential Material, or if they contain or refer to Documents, Testimony, or Information to be designated as Confidential Material, the Designating Party, by and through Counsel, shall either:
 - a. On the record at the deposition, designate the Testimony or exhibit(s) as Confidential Material, to the extent not already designated as Confidential Material, or
 - b. No later than 30 days after receiving a final version of the deposition transcript, inform Outside Counsel for all Parties, as well as counsel for any non-party that participated in the deposition (or, if such non-party was not represented by counsel, then the non-party) that the Testimony or exhibit(s) constitute Confidential Material. Absent agreement of the Parties during the 30-day period, the entire deposition Testimony, transcript, and exhibits shall be treated as Confidential Material under this Confidentiality Order during that period.
3. Persons attending a deposition who are not Qualified Persons may be excluded from the portions of the deposition during which Confidential Material is disclosed.

D. Written Pleadings, Motion Papers, and Discovery Materials.

A Designating Party may designate as Confidential Material the entirety or portions of written discovery requests and responses, including interrogatories and interrogatory answers, requests for admission and responses to requests for admission, and requests for production of

documents and things and responses to such requests, as well as pleadings, motions, affidavits, briefs, and other court submissions that quote, summarize, or contain Confidential Material.

E. Other Confidential Material.

With respect to Confidential Material produced in some form other than as described above, including, without limitation, compact discs or DVDs or other tangible items, the Designating Party must affix in a prominent place on the exterior of the container or containers in which the Information or item is stored the legend **CONFIDENTIAL**. If only portions of the Information or item warrant protection, the Designating Party, to the extent practicable, shall identify the portions that constitute Confidential Material.

F. Confidential Material Disclosed by a Non-Party.

With respect to Documents, Testimony, or Information produced or disclosed by a non-party, either the non-party or a Party may designate the Documents, Testimony, or Information as Confidential Material pursuant to this Confidentiality Order. A Party so designating material produced or disclosed by a non-party shall notify all other Parties and the producing non-party within 7 days of receipt of such Document, Testimony, or Information that the same or portions thereof constitute or contain Confidential Material. Absent agreement of the Parties and the producing third party, until the expiration of the 7 days, such Document, Testimony, or Information produced or disclosed by any such non-party shall be treated as Confidential Material under this Confidentiality Order.

G. Prior Production.

Confidential Material that was produced by a Party prior to entry of this Confidentiality Order and/or pursuant to an Offer of Confidential Access and/or under Local Patent Rule 2.2 shall be deemed designated as “**CONFIDENTIAL**.”

H. De-Designation Requests.

Nothing in this Confidentiality Order shall prohibit a Receiving Party from requesting that a Designating Party release Confidential Material from the confidentiality restriction for all purposes or for limited purposes (such as to show to certain designated persons). Any such requests and resulting permission shall be in writing and shall be considered by the Designating Party in a reasonable manner.

V. Required Treatment of Confidential Material.

- A. Confidential Material shall not be disclosed in any way to anyone for any purpose other than as provided in this Confidentiality Order.
- B. **Confidentiality.** Except as specifically provided in this Confidentiality Order, Counsel shall keep all Confidential Material disclosed or produced to them within their exclusive possession and control, shall take all necessary and prudent measures to maintain the confidentiality of such materials and information, and shall not permit unauthorized dissemination of such materials to anyone.

C. **Security.**

1. **Security Practices.** To avoid security risks inherent in certain current technologies and to facilitate compliance with the terms of this Confidentiality Order, and unless otherwise ordered or agreed upon in writing by the Designating Party whose Confidential Material is at issue, all Qualified Persons with access to Confidential Material (other than any court or government agency) shall use secure means, equivalent in substance to current third-party certifications of compliance with an industry-standard security framework, such as ISO (International Standards Organization), NIST (National Institutes of Standards and Technology), CIS (Center for Internet Security), or HITRUST, to store and transmit Confidential Material. In addition, any Qualified Person that hosts an e-discovery production containing Confidential Material shall employ continually at least the following industry-standard data-security practices:
 - a. **Encryption** of Confidential Material “at rest” (*i.e.*, in every location in which it is stored) and “in transit” (*i.e.*, whenever it is communicated in manners authorized under this Order between parties, or between a Party or its counsel and any vendor(s), expert witness, or other third party retained to assist such Party or its counsel in this Action).
 - b. **Access Controls.**
 - (i) **Role-based Access Controls** that use criteria (a) limiting access to Confidential Material to only those who need to know and (b) prohibiting access to all others.
 - (ii) **Password Security** requiring “strong” passwords as the term “strong” is understood in the data-security industry.
 - (iii) **Multi-factor Authentication** for remote access to Confidential Material and for administrative access to systems that process or store Confidential Material.
 - c. **Malware Protection** comprising industry-standard spam filters, anti-virus and anti-spyware software (including email URL and attachment scanning), firewalls, email encryption services, network security protocols, intrusion detection systems, and data loss prevention solutions.
 - d. **Asset Management** of current and historical inventories of hardware and software used to receive, store, manage, and transmit Confidential Material.

- e. **Ongoing Periodic Training** of all persons with access to Confidential Material, including regular reminders that such persons remain bound by the commitments set out in the copy of Exhibit A signed by them.
2. To the extent any Qualified Person has one or more current third-party certifications of compliance with an industry-standard security framework, such as ISO (International Standards Organization), NIST (National Institutes of Standards and Technology), CIS (Center for Internet Security), or HITRUST, that certification shall be deemed to satisfy the requirements of Section V.C.1 with respect to that person.
 3. **Breach.** In the event that unauthorized access to or acquisition of Confidential Material (other than a Party's own Confidential Material) is reasonably likely to have occurred (a "Breach"), the Designating Party must be notified immediately and appropriate remedial measures must be taken. If a Qualified Person that hosts an e-discovery production containing Confidential Material has suffered a breach, then the following requirements apply to that Qualified Person:
 - a. Each such Qualified Person shall take immediate necessary and prudent remedial measures, including measures in compliance with state and regulatory requirements, to prevent reoccurrence of a Breach and promptly shall inform the Designating Party of all facts relating to the Breach, including identification of all Confidential Material that may have been accessed or acquired in the Breach, and of all remedial measures taken in response to the Breach.
 - b. Each such Qualified Person also shall have available for any inspection requested by the Court all of the following industry-standard plans or protocols used or adopted by that person prior to the Breach:
 - (i) **Policies and Procedures.** *I.e.*, all components of any written information-security policy, procedure, plan, program, or cyber and privacy liability insurance.
 - (ii) **Assessments and Audits.** *I.e.*, any security and risk assessment, penetration test, vulnerability scan, or other analysis of the security of the person's network and data systems.
 - (iii) **Certifications.** Any certification of compliance with industry security frameworks, such as ISO, NIST, CIS, or HITRUST.
 - (iv) **Third Party Agreements.** The relevant security and confidentiality provisions of any agreement with a third

party with whom Confidential Material has been shared as permitted by this Order, as well as any other documentation demonstrating the third party's security measures and/or compliance with the agreement(s).

- D. **Access.** Access to and disclosure of Confidential Material shall be limited to those persons designated as Qualified Persons, below. Any Qualified Person who examines any Confidential Material shall not disseminate orally, or by any other means, any Documents, Testimony, or Information, in whole or in part, that is designated as Confidential Material other than as permitted by this Confidentiality Order.
- E. **Purposes of Use.** Confidential Material shall be used by a recipient thereof solely for the purposes of this Action (including any appeals) and not for any other action or any business, marketing, research-and-development, competitive, or other non-litigation purpose including, but not limited to, filing or prosecuting of any patent applications, any FDA communications or petitioning activity, or any United States or European Pharmacopoeia standard setting activity, without the express written consent of Counsel for the Designating Party or by order of the Court. The non-litigation purposes identified in the previous sentence are solely for purposes of clarity and illustration and are not exhaustive and shall not be read to expand the scope of permissible use of Confidential Material under this Confidentiality Order. Notwithstanding the foregoing:
1. Nothing in this Confidentiality Order shall limit any Producing Party or Designating Party's use of its own Documents, Testimony, or Information or shall prevent any Producing Party or Designating Party from disclosing its own Confidential Material to any person for any purpose. Disclosures as described in this Paragraph V.E.1 shall not affect any confidentiality designation made pursuant to the terms of this Confidentiality Order so long as the disclosure is made in a manner that is reasonably calculated to maintain the confidentiality of the designated Information, Testimony, or Document.
 2. This Confidentiality Order shall not bar any Counsel from rendering legal advice to such attorney's client that is based in part on the attorney's analysis or evaluation of materials designated as Confidential Material, provided, however, that in rendering such advice and otherwise communicating with such attorney's client, the attorney shall not disclose the substance of any materials designated as Confidential Material by a Designating Party contrary to the terms of this Confidentiality Order.
 3. This Confidentiality Order places no limitation on the disclosure of Confidential Material to any United States court or United States government agency in connection with investigation of any crime, and nothing in this Confidentiality Order shall preclude any authorized recipient of Confidential Material from disclosing such Confidential

Material to any United States court or United States government agency in connection with investigation of any crime.

4. Nothing in this Confidentiality Order shall preclude a Party from introducing into evidence at trial or any hearing any Confidential Material that is admissible under applicable law. The Parties shall meet and confer regarding the procedures for use of Confidential Material at trial or in any hearing and shall move the Court for entry of an appropriate order. Pending agreement on such procedures, a Party may disclose Confidential Material in open court only after giving reasonable notice to the Designating Party. At trial or in hearings, the Court may take such other measures or enter separate orders as the Court deems appropriate or upon request by any Party, to protect the Confidential Material sought to be introduced or admitted.

F. Use of Confidential Material in Court Prior to Trial.

1. A Party seeking to file any Confidential Material shall file a motion to seal, or otherwise restrict public access to, those materials pursuant to Local Civil Rules 5.3(c) and 7.1 and in accordance with the provisions of the United States District Court for the District of New Jersey's Electronic Case Filing Policies and Procedures. All such Confidential Material so filed shall be released from confidential treatment by the Court only upon further order of the Court or written agreement of the Parties.
2. The burden of proving to the Court that such material designated as Confidential Material should be sealed under Local Civil Rule 5.3 shall at all times remain with the Designating Party that initially produced the material and designated it as Confidential Material.
3. If the party filing the material is not the Designating Party, the filing party nonetheless is obligated when filing material designated as Confidential Material to meet the provisions of Local Civil Rule 5.3 to protect the Designating Party's materials. The Designating Party shall be responsible for filing any additional papers necessary to support the motion to seal.

- G. Public Or Other Proper Knowledge.** The restrictions contained in this Confidentiality Order shall not apply to Information that is or was available to the public, whether before or after disclosure under this Confidentiality Order, other than by an act or omission of the Receiving Party, or that is lawfully and independently acquired from a source not subject to this Confidentiality Order.

VI. Qualified Persons With respect to Confidential Material.

Confidential Material may be disclosed only to the following persons (referred to as "**Qualified Persons**" throughout this Confidentiality Order):

- A. Outside Counsel of record for any Party in this Action, and their respective legal, investigative, technical, administrative, and other support staff, engaged in the conduct of this Action on behalf of named Parties;
- B. Certain specified in-house personnel of the Parties, as follows:
 - 1. Qualified Persons identified under this Section VI.B may include:
 - a. Up to three (3) in-house counsel employed by any of Plaintiffs Janssen Pharmaceutical NV, Janssen Biotech, Inc., and/or a parent entity of either;
 - b. Up to three (3) in-house intellectual property personnel employed by Plaintiff Astex Therapeutics Ltd. and/or a parent entity; and
 - c. Up to three (3) in-house intellectual property personnel employed by Defendant Natco Pharma Ltd. and/or a parent entity.
 - 2. Each individual identified as a Qualified Person under this Section VI.B must:
 - a. Be an attorney or counsel, or, if the Party does not have any in-house attorney or counsel, a professional member of the Party's in-house legal, litigation, and/or intellectual property staff;
 - b. Have responsibilities in overseeing this Action; and
 - c. Not be primarily responsible for any direct marketing, financial competitive decision-making, or pricing competitive decision-making (not including decision making in litigation, including negotiating or executing an agreement settling litigation, including any financial terms of such an agreement, or advising regarding the nature and scope of litigation) concerning erdafitinib.
 - 3. Any Qualified Person designated under this Section VI.B must sign the Endorsement of Confidentiality Order attached at Exhibit A before accessing any Confidential Material. Outside Counsel for a Party shall provide copies of the signed endorsements to all other Parties.
 - 4. Any Qualified Person designated under this Section VI.B may disclose Confidential Material to their secretarial, paralegal, clerical, or legal assistant staff.
 - 5. In the event that any Qualified Person designated under this Section VI.B who has subscribed to Exhibit A ceases to have responsibilities related to this Action, that individual may be substituted upon written notification via email to all Parties along with an Endorsement of Confidentiality

Order (Exhibit A) completed and signed by the individual being substituted in.

6. Subject to the foregoing, the Parties designate the following in-house Qualified Person(s):
 - a. For Plaintiffs Janssen Pharmaceutical NV and Janssen Biotech, Inc., Isaac Olson, Angie Verrecchio, and Denise DeFranco.
 - b. For Defendant Astex Therapeutics Ltd., none identified at this time.
 - c. For Defendant Natco Pharma Ltd., none identified at this time.
 7. Any Party not now identifying its permitted number of in-house Qualified Person(s) may do so at a later date with notice to all Parties.
 8. No Confidential Material produced by Defendant Astex Therapeutics Ltd. may be disclosed to any Qualified Person under this Section VI.B unless and until it is used or relied upon in this Action.
- C. Independent experts (“**Experts**”) including their support staffs, retained by or for the Parties or their Counsel, including technical experts and accounting or financial experts, who are employed to furnish expert or technical services or to give expert testimony with regard to this Action and who are not otherwise affiliated with a Party, with the following qualifications:
1. Disclosure shall not be made to any Expert if Counsel for the Party retaining that expert has actual knowledge that the Expert has been found to have violated the terms of a protective order in any litigation or legal proceeding; and
 2. Any Expert to whom disclosure of Confidential Material is authorized must be informed of this Confidentiality Order and must sign a copy of the Endorsement of Confidentiality Order attached hereto as Exhibit A. Outside Counsel for a Party shall provide a copy of the signed endorsement to all other Parties.
- D. Persons or firms retained by any Party for the purpose of litigation support (*e.g.*, e-discovery vendors, contract review attorneys, translators, trial/jury consultants) or producing graphic or visual aids, if they signed a copy of the Endorsement of Confidentiality Order attached hereto as Exhibit A or are bound by a similar confidentiality obligation;

- E. Any person who:
 - 1. Is identified in the Confidential Material as an author (in whole or in part), source, addressee, custodian, or recipient of the Confidential Material;
 - 2. Had some prior involvement with the subject matter of the Confidential Material; or
 - 3. Already has or had a copy of the Confidential Material;
- F. Any person who has been designated as a Rule 30(b)(6) witness by the Designating Party;
- G. Any mediators or arbitrators selected to assist in resolution of this matter, and their personnel who are actively engaged in assisting them, if they have signed a copy of the Endorsement of Confidentiality Order attached hereto as Exhibit A;
- H. The Court, any appellate court(s), or any Court personnel, and persons (including necessary clerical personnel) recording, taking, or transcribing testimony or argument at any deposition, hearing, trial, or appeal of this Action, including any court reporters and videographers, to the extent Confidential Material is disclosed at a deposition or Court session which such reporter or videographer is transcribing or recording;
- I. Any United States court or United States government agency for the purpose of any criminal investigation, under seal or with other suitable precautions calculated to maintain confidentiality;
- J. Any other persons agreed to by the Designating Party, as long as such persons comply with the procedures of Sections VI and VII as applicable; and
- K. Any other persons permitted by the Court.

VII. Further Requirements With Respect to Qualified Persons

- A. Counsel for each Party shall maintain copies of all Endorsements of Confidentiality Order (Exhibit A) received, which shall be available for inspection by the Court.
- B. Any Confidential Material distributed or disclosed by Counsel for a Party to another Qualified Person shall be returned to the Party's Counsel who provided it to the Qualified Person or shall be destroyed at the completion of the Qualified Person's consultation or participation in this case. Upon the request of the Designating Party or the Court, each such Qualified Person shall execute an affidavit stating that all such Confidential Material and copies thereof have been returned or destroyed as required.

- C. The Court shall retain jurisdiction over any person or organization authorized, as set forth above, to receive Confidential Material as necessary to enforce the provisions of this Confidentiality Order.
- D. Unless otherwise specified, if any Party desires to disclose Confidential Material to any Expert pursuant to Section VI.C above, it must first identify in writing to the Outside Counsel for the Designating Party each such Expert.
 - 1. At the time the identity of the Expert is disclosed, the following shall also be furnished in writing to the Outside Counsel for the Designating Party:
 - a. The Expert's current resumé or curriculum vitae;
 - b. A list of any known consulting relationships that the Expert has had with any Party to this action within the last five (5) years (excluding non-testifying litigation consulting, the existence of which is protected by attorney work product immunity);
 - c. A list of cases in which the Expert has testified as an expert at trial or deposition within the last four (4) years; and
 - d. A copy of the Endorsement of Confidentiality Order attached hereto as Exhibit A signed by the Expert.
 - 2. Parties may begin disclosing Experts as soon as this Confidentiality Order is signed by the Parties.
 - 3. Outside Counsel for the Designating Party shall have five (5) business days from receipt of such notice to object in writing, and with an explanation of the basis for the objection, to the disclosure of Confidential Material to any Expert so identified.
 - a. Any Party that fails to object in writing with an explanation of the basis for the objection within five (5) business days of receiving such notice shall be deemed to have waived such objection, and the Parties shall be deemed to have agreed upon disclosure to the Expert.
 - b. If a timely objection is made, then the Parties shall have seven (7) business days after the objection is raised to use good faith efforts to reach an agreement regarding the proposed disclosure to the Expert, during which period of time disclosure may not be made absent an agreement. If agreement cannot be reached, the Party objecting to disclosure may apply to the Court for relief within ten (10) business days after it is determined that an agreement cannot be reached or after expiration of the 7-day period, whichever comes first. The burden shall be on the objecting Party to show the Court good cause why the disclosure should not be made.

- c. No Confidential Material may be disclosed to any proposed Expert until such time as the Parties agree or are deemed to have agreed upon disclosure to the Expert, or any timely objection has been resolved in favor of disclosure by agreement of the parties or order of the Court.
- E. Qualified Persons under Sections VI.A and VI.B are subject to the following additional requirements:
 - 1. Qualified Persons under Sections VI.A and VI.B, commencing as of the date the Qualified Person receives information designated as Confidential Material under this Confidentiality Order by an opposing Party in this Action and continuing for one year following a final termination of this Action including appeals, may not engage in:
 - a. Any patent prosecution concerning erdafitinib; or
 - b. Any FDA counseling or other work before or involving the FDA (including, *e.g.*, citizen petitions) regarding approval requirements for erdafitinib products.
 - 2. Notwithstanding the foregoing, nothing herein shall preclude Qualified Persons under Sections VI.A and VI.B from working on and participating in, directly or indirectly, any of the following:
 - a. All aspects of any inter partes review, post-grant review, re-issue, re-examination, requests for certificates of correction, or supplemental examination proceedings at the U.S. Patent and Trademark Office or the Patent Trial and Appeal Board (or in any appeal from any such proceedings in the Federal Circuit) for patents or applications concerning erdafitinib products, other than drafting or preparing claim amendments;
 - b. All aspects of any pre- or post-grant opposition proceedings or invalidation request proceedings before a foreign patent office or court for a patent or application concerning an erdafitinib product, other than drafting or preparing claim amendments;
 - c. The decision to file, abandon, or extend the term of a patent application without input on the claims being pursued or contemplating being pursued;
 - d. Proceedings or litigations relating to patent term extension under 35 U.S.C. § 156 *et seq.* or patent term adjustment under 35 U.S.C. § 154 *et seq.* for a patent or application concerning erdafitinib products;

- e. Obtaining or maintaining approval or exclusivity of a Party's own NDA, ANDA, or other FDA application (*e.g.*, by submitting patent certifications, or advising about launch dates or label carve-outs); or
- f. The listing of patents in the FDA's Orange Book publication.

VIII. **Inadvertent Production or Disclosure of Confidential Material.**

- A. Inadvertent or unintentional disclosure, without the required confidentiality designation, of any Document, Testimony, or Information that the Producing Party intended to designate as Confidential Material ("**Inadvertent Production**") shall not be deemed a waiver in whole or in part of the Producing Party's claim of confidentiality, either as to specific Documents, Testimony, or Information disclosed or as to the same or related subject matter. This Section VIII shall be interpreted to provide the maximum confidentiality protection allowed under applicable law.
- B. In the event that a Producing Party makes such an Inadvertent Production, that Party shall contact the Receiving Party within seven (7) days of the discovery of the Inadvertent Production, or as promptly as reasonably possible thereafter, and inform the Receiving Party or Parties in writing of the Inadvertent Production and the specific material at issue.
- C. Upon receipt of such notice, the Receiving Party shall treat the material identified in the notice as Confidential Material until (i) the Parties agree to nonconfidential treatment of the subject material, or (ii) the Court issues an order determining that the material does not qualify for protection as Confidential Material.
- D. As promptly as reasonably possible after providing such notice, the Producing Party shall re-produce the Confidential Material with the required legend. Within five (5) business days of receiving re-production, the Receiving Party shall return or destroy all copies of such Confidential Material that did not bear the confidentiality legend and confirm, in writing, that all such Confidential Material has been returned or destroyed. Each Receiving Party shall notify every person or organization that received copies of or access to the material identified in the notice that such material contains Confidential Material.

IX. **Challenges to Designations.**

- A. At all times, the Designating Party bears the burden of establishing the applicability of its designations.
- B. Nothing in this Confidentiality Order shall constitute a waiver of any Party's right to object to the designation or non-designation of Documents, Testimony, or Information as Confidential Material. A Party shall not be obligated to challenge the propriety of any designation of Confidential Information at the time the

designation is made, and failure to do so shall not preclude a subsequent challenge to the designation.

C. In the event that the Receiving Party objects to the designation of any Documents, Testimony, or Information as Confidential Material, Outside Counsel for the Receiving Party shall advise Outside Counsel for the Designating Party, in writing, of such objections, the specific Confidential Material (identified by Bates number, if possible) to which each objection pertains, and the specific reasons and support for such objections (the “**Designation Objections**”).

1. Outside Counsel for the Designating Party shall have seven (7) business days from receipt of the written Designation Objections to respond in writing as to whether the designations will be maintained or withdrawn.
2. If the Designating Party does not de-designate the challenged Confidential Material at issue, the parties shall meet in confer in good faith to discuss the Designation Objections and attempt to resolve the dispute.
3. If, after meeting and conferring in good faith, the Parties are unable to resolve the dispute regarding the Designation Objections, the Party challenging the designations may seek relief from the Court in accordance with Local Civil Rule 37.1 and through the joint letter procedure set forth in Section 4(a) of Magistrate Judge José R. Almonte’s Case Management Order posted at <https://www.njd.uscourts.gov/sites/njd/files/JRAPreferences.pdf>.

D. In the event that any Designation Objections are made under Section IX.C, the material at issue shall be treated as Confidential Material unless and until:

1. The Parties reach a written agreement not to so treat the material, or
2. The Court issues an order determining that the material does not qualify for protection as Confidential Material.

X. **Redactions.**

A. **Redactions Permitted.** To protect against unauthorized disclosure of Confidential Material, and to comply with all applicable state and federal laws and regulations, the Producing Party may redact from produced documents, materials, and other things, the following items, or any other item(s) protected from disclosure by statute or decisional authority or agreed upon by the Parties or ordered by the Court:

1. Information that is subject to the attorney-client privilege, work-product immunity, common interest protection, or any other applicable privilege or immunity;
2. Information that is subject to third-party confidentiality obligations;

3. Information that is governed by any applicable privacy law or regulation, including the following:
 - a. The Social Security numbers, tax identification numbers, and other personal identifying information of employees in any records; and
 - b. The names, street addresses, Social Security numbers, tax identification numbers, and other personal identifying information of patients, health care providers, and individuals in clinical studies or adverse event reports. Other general identifying information, however, such as patient or health provider numbers, shall not be redacted unless required by state or federal law;
4. Commercially sensitive or proprietary non-responsive information, including information relating to products not at issue in this Action and commercially sensitive or proprietary business, financial, marketing, research and development, or intellectual property information that is nonresponsive.

B. Methods of Redaction.

1. The Producing Party may withhold entire non-responsive attachments in a document family and may produce slipsheets in their place.
2. Each redaction in a TIFF-image shall be indicated clearly on the image as being based on “Privilege” or “Other.”
3. For native files requiring redaction, redacted text shall be replaced with the terms “Privilege” or “Other,” and the Producing Party shall produce the redacted file either in native format or in an authorized TIFF-image format.
4. For metadata fields requiring redaction, field content shall be replaced by the term “Redacted,” and the modified field shall be included in any required .dat file.

C. Confidentiality of Certain Unredacted Names. Pursuant to 21 C.F.R. §§ 314.430(e) & (f) and 20.63(f), the names of any person or persons reporting adverse experiences of patients and the names of any patients that are not redacted shall be treated as Confidential Material, regardless of whether the Document containing such names is designated as Confidential Material.

D. Challenges to Redactions. Notwithstanding any of the foregoing provisions, nothing contained herein shall be construed as a waiver of a party’s ability to challenge such redactions. The burden as to the propriety of any redaction remains on the Producing Party at all times. Any objections to redactions shall be raised and resolved following the same procedure set forth in Section IX.C for objecting to confidentiality designations.

XI. Outside Requests for Confidential Material.

- A. If another court or an administrative agency, or a party in another litigation, requests, subpoenas, or orders the disclosure of Confidential Material from a Party that has obtained such material under the terms of this Confidentiality Order, the Party so requested, subpoenaed, or ordered shall, if not prohibited under applicable law, notify the Designating Party by electronic mail transmission, express mail, or overnight delivery to Counsel of record for the Designating Party not later than ten (10) days prior to producing or disclosing any Confidential Material, and shall furnish such Counsel with a copy of the requests, subpoena, or order. The recipient of the requests, subpoena, or order shall not disclose any Confidential Material pursuant to the requests, subpoena, or order prior to the date specified for production on the requests, subpoena, or order.
- B. Upon receipt of this notice, the Designating Party may, in its sole discretion and at its own cost, move to quash or limit the request, subpoena, or order, otherwise oppose the disclosure of the Confidential Material, or seek to obtain confidential treatment of such Confidential Material, to the fullest extent available under law, by the person or entity issuing the request, subpoena, or order. The Party who received the request, subpoena, or order shall not oppose or otherwise interfere with the Designating Party's effort to quash or limit the request, subpoena, or order.

XII. Disposition of Confidential Material.

- A. Each Receiving Party shall, within sixty (60) calendar days of final termination of this Action (including all appeals), either return to the Designating Party or destroy all of the Designating Party's Confidential Material in the Receiving Party's possession.
- B. The return or destruction of Confidential Material under this Section shall include, without limitation, all copies and duplicates thereof, including copies on any litigation-support review application, which shall not be considered work product for purposes of this Section XII.
- C. The Parties shall certify, within sixty-seven (67) calendar days of final termination of this Action (including all appeals), that all Confidential Material required to be returned or destroyed under this Section XII has been so returned or destroyed. This certification also shall include a statement that, to the Party's knowledge, any Confidential Material distributed or disclosed by the Party's Counsel to other Qualified Persons has been returned or destroyed in compliance with Section VII.B of this Confidentiality Order.
- D. As an exception to the requirements of this Section, and unless otherwise ordered by the Court, Counsel for a Party may retain: (a) copies of pleadings or other papers that have been filed with the Court and that are Confidential Material or that reflect, reference, or contain Confidential Material, together with any exhibits

thereto; (b) each deposition transcript together with the exhibits marked at the deposition; (c) each expert report together with any exhibits thereto; (d) each set of written discovery requests and responses (but not Confidential Material produced in response to discovery requests unless otherwise qualified for retention); (e) each trial or hearing transcript, and each exhibit used at trial or in a hearing; (f) each item of correspondence; (g) any mediation briefs and exhibits thereto; and (h) all drafts, memoranda, and other Documents constituting work product which were based upon or which include Confidential Material. The terms and provisions of this Confidentiality Order shall continue to apply to any such materials retained by Counsel. In the event that Counsel maintains such Documents, it shall not disclose material containing any Confidential Material to another Party or third party absent subpoena or court order.

- E. Nothing in the Confidentiality Order shall be construed to require Counsel for a Party to purge its email systems, document management systems, or backup tapes.

XIII. No Waiver of Any Privilege Upon Unintentional Production of Privileged Information.

- A. The Parties have agreed that, in discovery in this Action, they do not intend to disclose information subject to a claim of attorney-client privilege, attorney work product protection, common interest protection, or any other privilege or immunity.
1. This Confidentiality Order does not affect or constitute a waiver of any Party's right to withhold or redact information protected from disclosure by the attorney-client privilege, physician-patient privilege, work product doctrine, common interest protection, or any other applicable privilege or state, federal, or foreign law or regulation.
 2. **Rule 502(d).** Pursuant to Federal Rule of Evidence 502(d), and 28 U.S. Code § 1738, and Federal Rule of Civil Procedure 26(b)(5)(B), the production or disclosure of any discovery material that a Producing Party thereafter claims should not have been produced or disclosed based on privilege or work product protections ("**Disclosed Privileged Information**"), shall not constitute or be deemed a waiver or forfeiture in whole or in part—in this Action or any other action—of any claim of attorney-client privilege or work product immunity that the Producing Party would otherwise be entitled to assert with respect to the Disclosed Privileged Information and its subject matter, regardless of the circumstances of the production or disclosure. As set forth below, such Disclosed Privileged Information shall be returned to the Producing Party or destroyed upon request. This Order shall be interpreted to provide the maximum protection allowed by Federal Rule of Evidence 502(d). Nothing contained herein is intended to or shall serve to limit a party's right to conduct a review of documents, electronically stored information, or other information (including metadata) for relevance, responsiveness,

and/or segregation of privileged and/or protected information before production.

3. **Rule 502(b).** Federal Rule of Evidence 502(b) is inapplicable to Disclosed Privileged Information, which shall receive the maximum protection afforded by Federal Rule of Evidence 502(d). Under Federal Rule of Evidence 502(d) and 28 U.S. Code § 1738, this Order shall be enforceable and granted full faith and credit in all other state and federal proceedings. Any subsequent conflict-of-law analysis shall apply the law most protective of privilege and work product.
- B. **Attorney's Ethical Responsibilities.** Nothing in this Confidentiality Order overrides any attorney's ethical responsibilities to refrain from examining or disclosing materials that the attorney knows or reasonably should know to be privileged and to inform the Producing Party that such materials have been produced. Any party receiving materials that, on their face, appear to be covered by a privilege, shall not copy, distribute, or otherwise use in any manner such materials and shall provide prompt notice of the disclosure to the Producing Party to afford the Producing Party the opportunity to request return of the materials.
- C. If a Producing Party notifies the Receiving Party of Disclosed Privileged Information, the Receiving Party shall immediately cease any copying, distribution, or other use of the Disclosed Privileged Information, and shall instruct all persons to whom the Receiving Party has disseminated a copy of the Disclosed Privileged Information to do the same and to return, destroy, or (in the case of electronically stored information) delete the Disclosed Privileged Information. Additionally, within ten (10) business days, the Receiving Party must do the following:
1. Return, destroy, or delete all copies of such Disclosed Privileged Information (including all notes or other work product of the Receiving Party reflecting the contents of the Disclosed Privileged Information) within their possession, custody, or control;
 2. Take reasonable steps to retrieve or confirm destruction or deletion of any disclosed copies of the Disclosed Privileged Information if the Receiving Party disclosed it before being notified; and
 3. Confirm in writing that all such Disclosed Privileged Information has been returned, destroyed, or deleted.
- D. For purposes of this Confidentiality Order, Disclosed Privileged Information that has been stored by the Receiving Party on a source of electronically stored information that is not reasonably accessible, such as backup storage media, is sequestered. If such data is retrieved, the Receiving Party must promptly take steps to delete the restored Disclosed Privileged Information.

- E. Return, destruction, or deletion of Disclosed Privileged Information shall be without prejudice to the Receiving Party's right to seek an order from the Court directing production of the Disclosed Privileged Information on the ground that the claimed privilege, work-product protection, or immunity is invalid, inapplicable, or waived, provided, however, that the production of the Disclosed Privileged Information in the course of this Action shall not be a ground for asserting waiver of the privilege, protection, or immunity.
- F. If the Receiving Party contests the claim of attorney-client privilege or work product protection, the Receiving Party may—within ten (10) business days of receipt of the notice of disclosure—seek relief from the Court through the joint letter procedure set forth in Section 4(a) of Magistrate Judge José R. Almonte's Case Management Order posted at <https://www.njd.uscourts.gov/sites/njd/files/JRAPreferences.pdf>.
 - 1. Such a submission shall be filed or lodged conditionally under seal subject to the requirements of the United States District Court for the District of New Jersey for sealing filings. In conjunction with any such submission, the Parties shall present the Disclosed Privileged Information in question to the Court under seal, subject to the requirements of the United States District Court for the District of New Jersey for sealing filings.
 - 2. In any such submission, the Producing Party shall retain the burden of establishing its privilege or work product claims.
 - 3. In such a submission or dispute, the Receiving Party shall not rely upon in any manner or assert as a ground for ordering production of Disclosed Privileged Information the facts or circumstances of the production of the Disclosed Privileged Information.
 - 4. One copy of each Document containing the Disclosed Privileged Information in question may be maintained by Outside Counsel for the Receiving Party until entry of an order by the Court resolving the dispute. Outside Counsel for the Receiving Party shall only use the one retained copy for purposes of preparing the joint submission and matters related thereto. Pending resolution of the dispute, the Receiving Party must not use the Disclosed Privileged Information in any other way or disclose it to any person other than those required by law to be served with a copy of the sealed joint submission.
 - 5. Nothing in this Section shall limit the right of any Party to petition the Court for an *in camera* review of the Disclosed Privileged Information.

XIV. **Expert Materials Excluded from Discovery**

Notwithstanding Fed. R. Civ. P. 26(b)(4)(C)(i), (ii) and (iii), the Parties agree that the following materials will be excluded from discovery in this case: Expert witnesses' notes, drafts,

and communications with Counsel, with the exception that discovery shall be permitted into communications of facts or data on which an Expert relies in forming an opinion.

XV. Confidentiality Order Applicable Upon Filing With the Court

Upon filing this Confidentiality Order with the Court, the Parties agree to treat it as “So Ordered,” subject to any future modifications by agreement of the Parties or by order of the Court.

XVI. Confidentiality Order Survives Termination of Action.

After the termination of this Action by entry of a final judgment or order of dismissal (including without limitation any appeals and after the time for filing all appellate proceedings has passed), the provisions of this Confidentiality Order shall continue to be binding. This Confidentiality Order is, and shall be deemed to be, an enforceable agreement between the Parties, their agents, and their attorneys. The Parties agree that the terms of this Confidentiality Order shall be interpreted and enforced by this Court.

Dated: November 17, 2023.

Respectfully submitted,

By: /s/ Keith J. Miller

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So Ordered this ____ day of November, 2023.

HON. JOSÉ R. ALMONTE, U.S.M.J.

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

JANSSEN PHARMACEUTICA NV,
JANSSEN BIOTECH, INC., and
ASTEX THERAPEUTICS LTD.,

Plaintiffs,

v.

NATCO PHARMA LTD.,

Defendant.

Civil Action No. 2:23-cv-03959-BRM-JRA

Hon. José R. Almonte

**ENDORSEMENT OF
CONFIDENTIALITY ORDER**

**(EXHIBIT A TO DISCOVERY
CONFIDENTIALITY ORDER)**

I hereby attest that I understand that Information, Testimony, or Documents designated as Confidential Material are provided to me subject to the Discovery Confidentiality Order dated _____, 2023 (the “Order”), in the above-captioned litigation (“Litigation”); that I have been given a copy of and have read the Order; and that I agree to be bound by its terms. I also understand that my signature below indicates my agreement to be bound by the Order and is a prerequisite to my review of any Information, Testimony, or Documents designated as Confidential Material pursuant to the Order.

I further agree that I shall not use Confidential Material for any purpose other than as authorized in the Order and that, except as explicitly authorized in the Order, I shall not disclose Confidential Material, in any form whatsoever, to others.

I further agree to return or destroy Confidential Material in my possession, custody, or control in the manner and time specified by the Order.

I further agree and attest to my understanding that my obligation to honor the confidentiality of such Confidential Material will continue even after this Litigation concludes.

I further agree and attest to my understanding that, if I fail to abide by the terms of the Order, I may be subject to sanctions, including contempt of court, for such failure. I agree to be subject to the jurisdiction of the United States District Court for the District of New Jersey for the purposes of any proceedings relating to enforcement of the Order. I further agree to be bound by and to comply with the terms of the Order as soon as I sign this Agreement, regardless of whether the Order has been entered by the Court.

Date: _____ By: _____