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Attorneys for Defendant
NOVARTIS PHARMACEUTICALS
CORPORATION

13 UNITED STATES DISTRICT COURT
14 EASTERN DISTRICT OF CALIFORNIA

16 Kristi Lauris, Individually and as Successor
17 In Interest to the Estate of Dainis Lauris;
18 Kristi Lauris as Guardian ad Litem for
L.L.; and Taylor Lauris,

19 Plaintiffs,

20 vs.

21 Novartis AG, a Global Healthcare
22 Company; Novartis Pharmaceuticals
Corporation, a Delaware Corporation,

23 Defendants.

Case No. 1:16-cv-00393 LJO-SAB

ORDER RE STIPULATED PROTECTIVE
AND CONFIDENTIALITY ORDER

(E.D. Cal. Local Rule 141.1(b)(1))

Magistrate Judge: The Hon. Stanley A. Boone
Courtroom: 9

1 Plaintiffs Kristi Lauris (on behalf of herself and as successor in interest to the estate of
2 Dainis Lauris and as guardian ad litem for L.L.) and Taylor Lauris, and Defendants Novartis AG
3 (“NAG”) and Novartis Pharmaceuticals Corporation (“NPC”) (collectively “Defendants”) submit
4 an agreed Stipulated Protective and Confidentiality Order. The parties hereby stipulate to, and
5 jointly request that the Court enter, the Stipulated Protective and Confidentiality Order.

6 THIS STIPULATED ORDER IS ENTERED INTO by the undersigned counsel for
7 Plaintiffs and for Defendants Novartis Pharmaceuticals Corporation (NPC) and Novartis AG
8 (NAG) to facilitate the prompt resolution of disputes over confidentiality, and to expedite the
9 exchange of discovery materials among the parties to this Order, and the undersigned jointly
10 propose that the Court enter this Stipulation as an Order (hereinafter, “Protective Order”).

11 THEREFORE, the undersigned having so stipulated, this Court, having determined that
12 good cause exists to enter a Protective Order to cover confidential information,

13 It is hereby **ORDERED** and **ADJUDGED**, that:

- 14 (1) For purposes of this Protective Order, any Party may designate as “Confidential Material”
15 any information the Party reasonably and in good faith believes constitutes and reveals
16 confidential trade secrets, proprietary business information, or non-public, personal,
17 client, or customer information concerning individuals or other entities (including, but not
18 limited to Social Security numbers, home telephone numbers and addresses, and medical
19 information) that is contained in any document, written discovery response, testimony, or
20 other material produced or provided by that Party or its representative(s) to the other
21 Party, whether provided voluntarily, pursuant to formal discovery procedures, or
22 otherwise.
- 23 (2) For the purposes of this Protective Order, “Confidential Material” shall also include any
24 Protected Data, as defined hereinafter. Certain Protected Data may be subject to
25 alternative or additional protections beyond those afforded Confidential Information, in
26 which event the parties shall meet and confer in good faith, and, if unsuccessful, shall
27 move the Court for appropriate relief.
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- (3) “Protected Data” shall refer to any information that a party reasonably believes in good faith to be subject to federal, state or foreign data protection laws or other privacy obligations. Protected Data constitutes highly sensitive materials requiring special protection. Examples of such data protection laws include but are not limited to The Gramm-Leach-Bliley Act, 15 U.S.C. § 6801 et seq. (financial information); The Health Insurance Portability and Accountability Act and the regulations thereunder, 45 CFR Part 160 and Subparts A and E of Part 164 (medical information); Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data, 1995 O.J. (L281/31) (European Union personal information); the Federal Data Protection Act of 1992 (Swiss personal information); and Personal Information Protection and Electronic Documents Act (PIPEDA), S.C. 2000, c. 5 (Canada personal information).
- (4) Any Party may designate a document as Confidential Material by stamping it “Confidential,” or “Subject to Protective Order.” All pages of any document that bears such a legend are subject to this Confidentiality and Protective Order. The Party shall affix the stamp in such a manner so as not to obscure the text of the document.
- (5) To the extent that matter stored or recorded in the form of electronic or magnetic media (including information, files, databases or programs stored on any digital or analog machine-readable device, computers, Internet sites, discs, networks or tapes) (“Computerized Material”) is produced by any party in such form, the producing Party may designate such materials as Confidential by marking the container that the media is produced in “Confidential.” Whenever any party to whom Computerized Material designated as Confidential is produced reduces such material to hardcopy form, that party shall mark the hardcopy form with the “Confidential” designation.
- (6) If responses to interrogatories, requests for admission, or other written responses to discovery quote, summarize, or contain Confidential Material, the Parties may designate them as Confidential Material by marking the face of any such response with one of the

1 legends set forth in paragraph (2) above and indicating the page and line references of the
2 material that is to be subject to this Protective Order.

3 (7) A Party may designate the transcript of any deposition in this Action or any portion
4 thereof, including exhibits thereto, as Confidential Material by either so advising the court
5 reporter and the Parties on the record during the taking of the deposition or within thirty
6 (30) days after receipt of the deposition transcript by written designation served upon the
7 Parties. If all or any portion of a deposition is designated as being subject to this
8 Protective Order, the court reporter and any Party possessing any transcripts shall label the
9 cover page of each transcript or copy thereof to state that the deposition includes
10 Confidential Material, and shall label as confidential each of the pages of the transcript or
11 exhibits that contain Confidential Material.

12 (8) Any inadvertent production of any confidential or proprietary material will not result in or
13 be construed as a waiver, in whole or in part, of (a) the producing Party's claims of
14 confidentiality either as to the specific information inadvertently disclosed or more
15 generally as to the subject matter of the information disclosed, or (b) the party's right to
16 designate the material as confidential pursuant to this Protective Order. In the event that a
17 Party inadvertently produces any Confidential Material without attaching one of the
18 legends described in paragraph (2) above, the Party may subsequently designate the
19 material as Confidential at any time by forwarding to the opposing Party copies of the
20 material bearing one of the legends required by paragraph (2) and requesting that the
21 opposing Party destroy all prior copies of the Confidential Material. Upon receipt of such
22 a request, the opposing Party shall destroy all copies of the Confidential Material
23 produced inadvertently and replace them with copies bearing the appropriate
24 confidentiality legend.

25 (9) Written and oral communications between or among counsel for the Parties that refer to or
26 discuss Confidential Material automatically shall be subject to this Protective Order.
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1 (10) Confidential Material shall be treated by the Parties and their counsel as being confidential
2 and private. Any copy made of Confidential Material shall have the same status as the
3 original. The disclosure and use of Confidential Material shall be confined to the
4 permissible disclosures and uses set forth below. Any Confidential Material produced by
5 the Parties shall be used (if otherwise relevant and admissible) solely in this case,
6 including any appeals. Confidential Material shall not be used in any other legal action or
7 proceeding or for any other purpose without further order of this Court. All other
8 disclosure and use of Confidential Material during the pendency of this Action or after its
9 termination is hereby prohibited.

10 (11) Confidential Material may be disclosed only to the following persons and only insofar as
11 it is reasonably necessary to the effective prosecution of the Parties' claims and defenses:

- 12 (a) Parties, their representatives, in-house counsel and regular employees who are
13 actively engaged in, or actively overseeing this case or involved in complying
14 with NPC's legal obligations to provide information to the Food and Drug
15 Administration;
- 16 (b) Counsel of record for this case, including their associated attorneys, paralegal
17 and secretarial personnel, and other support staff;
- 18 (c) Experts and consultants (including their employees) who are retained by a
19 Party to assist in the litigation of this case;
- 20 (d) Third-party contractors and their employees who are retained by one or more
21 Parties to provide litigation-support or copy services in this case;
- 22 (e) Witnesses or prospective witnesses in this case;
- 23 (f) Court reporters and other persons involved in recording deposition testimony
24 in this case;
- 25 (g) Court personnel of the United States District Court for the Eastern District of
26 California, or, if on appeal, of The United States Court of Appeals for the
27 Ninth Circuit;
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- 1 (h) Jurors in this case; and
2 (i) The Food and Drug Administration, to the extent NPC is required to disclose
3 any Confidential Material by law.

4 Counsel for each Party disclosing Confidential Material in accordance with this paragraph
5 shall (i) advise each person to whom such disclosure is made (except Court personnel,
6 jurors, and the Food and Drug Administration) of the terms of this Protective Order and of
7 the obligation of each such person to comply with those terms and (ii) provide a copy of
8 this Protective Order to each such person. Prior to the disclosure of any Confidential
9 Information to any person identified in subparagraphs c, d, e, and f above, such person
10 shall sign an Acknowledgment, in the form attached hereto as Exhibit 1, acknowledging
11 that he or she has read this Protective Order and shall abide by its terms. Counsel shall
12 maintain a list of persons to whom confidential materials are disclosed (excluding jurors,
13 Court personnel, and the Food and Drug Administration). Upon learning of any
14 disclosure of Confidential Material to any person not authorized by this paragraph to
15 receive Confidential Material, the Party who so learns shall immediately (i) inform in
16 writing the Party from which the Confidential Material was originally received of such
17 disclosure, including to whom the material was disclosed, and (ii) take all necessary steps
18 to retrieve as soon as possible each and every copy of all Confidential Material from the
19 unauthorized person and any person to whom the unauthorized person disclosed the
20 Confidential Material.

- 21 (12) Documents bearing confidentiality designations shall not be used as exhibits at trial. The
22 Parties shall redact confidentiality designations from any documents to be used as exhibits
23 at trial and do so in a manner that ensures the redaction of the confidentiality designation
24 is not visible. Alternatively, before trial, and upon request, the producing Party shall
25 provide copies of such documents free of any confidentiality designation for use at trial.
26 Such documents shall be used only for trial purposes and shall be destroyed or returned,
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1 along with any and all copies made, to the producing Party after this case is finally
2 determined as to the Party to whom the documents were produced.

3 (13) Each Party agrees that in the event it is served by a non-party with a subpoena or request
4 for production of Confidential Material originally received from another Party, it will give
5 sufficient notice to allow that Party a reasonable opportunity to intervene to oppose such
6 production. The notice shall include a description of the material sought, the date and
7 location for compliance with the subpoena or request, the identity of the requester of the
8 Confidential Material, the docket number of the matter where requested and all other
9 information reasonably necessary to intervene and oppose such production.

10 (14) Personally identifiable information that a Party has designated as Protected Data based on
11 its reasonable and good faith belief that the information is subject to federal, state or
12 foreign data protection laws, data privacy laws, or other privacy obligations, or any of the
13 information contained therein, shall be handled by the receiving Party with highest care,
14 including but not limited to the procedures that they would employ to protect their own
15 personally identifiable information; and the documents produced shall be stored and
16 secured in a manner designed to prevent access to persons other than the above-listed
17 permitted individuals, and that all such information stored in electronic form shall be
18 password protected.

19 (15) Should any Party to whom Confidential Material is disclosed object to the designation of
20 that material as proprietary, confidential, or otherwise protected, it shall make a good-faith
21 effort to resolve the dispute informally with the disclosing Party. Except where good
22 cause is shown, all objections to the designation of documents as Confidential Material
23 must be interposed in writing no later than thirty (30) days after the close of merits
24 discovery, or such objections shall be deemed waived. Should the Parties be unable to
25 resolve the dispute, the Party opposing the inclusion of such material under this Protective
26 Order, within a reasonable time, may apply in writing to the Court for a ruling that the
27 information should not be entitled to protection under this Protective Order. The Party
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1 designating the material as confidential shall have the burden of proving that said material
2 is subject to protection. Until such time as the Court rules on the motion, the material that
3 is the subject of the dispute shall continue to be subject to this Protective Order.

4 **(16) CLAWBACK OF PRIVILEGED MATERIAL**

5 (16.1) To facilitate the expeditious production of voluminous documents, the parties
6 agree that a producing Party may produce documents without detailed, or any,
7 review to determine whether a privilege or other immunity from discovery applies
8 to some of the documents. Any disclosure of a privileged document within a
9 category of documents that was either not reviewed or was only reviewed by
10 computerized means will constitute an inadvertent production for the following
11 paragraphs.

12 (16.2) The inadvertent production by any Party in the course of discovery in these
13 proceedings of a document subject to a claim of privilege, work product, or other
14 applicable privilege or protection, will not result in a waiver of any of the
15 foregoing protections, whether in these or any other proceedings, for the produced
16 document or any other withheld document covering the same or similar subject
17 matter, pursuant to Federal Rule of Evidence 502(d).

18 (16.3) If a Party believes that it has inadvertently produced any such privileged or
19 protected materials, it shall promptly notify in writing the receiving Parties of the
20 claim of privilege. Upon such notice, the receiving Parties shall promptly: (1) use
21 commercially reasonable efforts to locate and destroy all copies of the material in
22 their possession, custody or control, including material stored in any litigation-
23 support or other database and all notes or other work product reflecting the content
24 of the material, and notify the producing Party that they have done so; and (2) take
25 all commercially reasonable steps to retrieve and destroy all copies of the
26 inadvertently produced material or documents from other persons, if any, to whom
27 such documents or materials were distributed. Receiving counsel shall certify in
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1 writing to the producing party's counsel that any notes or other work product
2 reflecting the inadvertently disclosed document's contents have been destroyed by
3 counsel, the receiving party, and any experts or others in their employment. If,
4 however, a receiving Party disputes the producing Party's assertion of privilege,
5 the receiving Party shall notify the producing Party in writing within 15 business
6 days of receiving the producing Party's notice. Within 30 business days of
7 receiving such notice of dispute, the Parties shall meet and confer to resolve the
8 dispute. If they are unable to resolve their dispute, the receiving Party may submit
9 the issue to the Court. In any such submission, the disputed documents or material
10 shall be filed, if at all, under seal.

11 (17) When a Party wishes to use a document that has been designated as confidential in support
12 of a motion or other filing with the Court, it will attempt to consult with the Party that has
13 made the confidentiality designation (a) to resolve a way to present the evidence without
14 the necessity of filing it with the Court; or (b) if no such resolution can be reached, to
15 arrange for appropriate protection under seal.

16 (18) This Protective Order shall not prevent the Parties from using or disclosing their own
17 documents and other materials in any manner, notwithstanding their designation as
18 Confidential Material subject to this Protective Order. The use or disclosure by a Party of
19 its own documents or materials shall not terminate, waive or otherwise diminish in any
20 way the status of such documents or materials as Confidential Materials subject to this
21 Protective Order.

22 (19) Upon the final determination, including any appeals related thereto, all Confidential
23 Material of an opposing Party should be returned or destroyed. Within thirty (30) days
24 after the date of final determination, all attorneys in possession of Confidential Material
25 shall return all Confidential Material to the disclosing Party or, alternatively, shall
26 immediately destroy all such material. This provision does not apply to materials that
27 Defendants are required to maintain and report pursuant to statutory and regulatory
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obligations, such as adverse event information submitted to the FDA. All counsel of record shall, within forty-five days of this final determination, certify that all Confidential Material, including any such material disclosed to any other entity, has been returned or destroyed. The sole exception to the requirements described above is that information that has been incorporated into attorney work product or other privileged documents need not be returned or destroyed. Such information shall be retained by the person to whom the information was produced, and shall be treated as Confidential Material in accordance with this Order.

(20) This Protective Order shall not enlarge or affect the proper scope of discovery in this or any other litigation, nor shall this Protective Order imply that material designated (or not designated) as Confidential Material under the terms of this Protective Order is properly discoverable, relevant or admissible in this or any other litigation.

(21) Each Party shall retain all rights and remedies available to it under the law for the enforcement of this order against anyone who violates it.

(22) The restrictions of this Protective Order shall continue to apply after this action is finally determined and the Court shall retain jurisdiction for all purposes in connection therewith. All persons receiving or given access to Confidential Material in accordance with the terms of this Protective Order consent to the continuing jurisdiction of the Court for the purposes of enforcing this Protective Order and remedying any violations thereof.

1 Dated: October 7, 2016

/s/ Sandra A. Edwards

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Dated: October 7, 2016

/s/ Julie Y. Park
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Dated: October 7, 2016

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Attorneys for Plaintiffs

ORDER

Pursuant to the stipulation of the parties, IT IS HEREBY ORDERED that:

1. The protective order is entered;
2. The parties are advised that pursuant to the Local Rules of the United States

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District Court, Eastern District of California, any documents which are to be filed under seal will require a written request which complies with Local Rule 141; and

3. The party making a request to file documents under seal shall be required to show good cause for documents attached to a nondispositive motion or compelling reasons for documents attached to a dispositive motion. Pintos v. Pacific Creditors Ass'n, 605 F.3d 665, 677-78 (9th Cir. 2009).

IT IS SO ORDERED.

Dated: October 11, 2016


UNITED STATES MAGISTRATE JUDGE

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EXHIBIT 1

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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA

Kristi Lauris, Individually and as Successor
In Interest to the Estate of Dainis Lauris;
Kristi Lauris as Guardian ad Litem for
L.L.; and Taylor Lauris,

Plaintiffs,

vs.

Novartis AG, a Global Healthcare
Company; Novartis Pharmaceuticals
Corporation, a Delaware Corporation,

Defendants.

Case No. 1:16-cv-00393 LJO-SAB

**ACKNOWLEDGMENT AND AGREEMENT
TO BE BOUND BY PROTECTIVE
AND CONFIDENTIALITY ORDER**

The undersigned agrees and declares under penalty of perjury the following:

I hereby attest that information or documents designated confidential are provided to me subject to the Stipulated Protective and Confidentiality Order (the "Order") that was issued by the United States District Court for the Eastern District of California on _____, 2016, in the above-captioned case. I have read this Order in its entirety and agree to comply with and to be bound by all the terms of this Order. I understand that my execution of this Acknowledgment, indicating my agreement to be bound by this Order, is a prerequisite to my review of any information or documents designated as confidential pursuant to the Order. I also understand and acknowledge that failure to so comply could expose me to sanctions and punishment in the nature of contempt. I solemnly promise that I will not disclose in any manner any information or item that is subject to this Order except in strict compliance with the provisions of this Order.

I further agree to submit to the jurisdiction of the United States District Court for the Eastern District of California for the purpose of enforcing the terms of this Order, even if such enforcement proceedings occur after termination of these proceedings.

Date: _____
City and State where sworn and signed: _____
Printed Name: _____
Signature: _____