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UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Edith Ramirez, Chairwoman**
Julie Brill

1. Respondent Novartis is a corporation organized, existing and doing business under and by virtue of the laws of the Swiss Confederation with its headquarters address located at Lichtrasse 35, Basel, Switzerland, V8 CH4056, and the address of its United States subsidiary, Novartis Corporation, located at 230 Park Avenue, New York, New York.

2. GlaxoSmithKline plc is a corporation organized, existing and doing business under and by virtue of the laws of the United Kingdom of Great Britain and Northern Ireland with its headquarters

E. “Acquisition” means Novartis’ acquisition of certain assets of Glaxo as described in the Acquisition Agreement.

F. “Acquisition Agreement” means the *Sale and Purchase Agreement* dated as of April 22, 2014, and the *Deed of Amendment and Restatement* dated as of May 29, 2014, between GlaxoSmithKline plc and Novartis AG that were submitted to the Commission. The Acquisition Agreement is contained in Non-Public Appendix II to this Order.

G. “Acquisition Date” means the date on which the Acquisition is consummated.

H. “Agency(ies)” means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term “Agency” includes, without limitation, the United States Food and Drug Administration (“FDA”) and the European Medicines Agency (“EMA”).

I. “Application(s)” means all of the following: “New Drug Application” (“NDA”), “Abbreviated New Drug Application” (“ANDA”), “Supplemental New Drug Application” (“SNDA”), or “Marketing Authorization Application” (“MAA”), the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314 et seq., and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the Respondent and the FDA related thereto. The term “Application” also includes an “Investigational New Drug Application” (“IND”) filed or to be filed with the FDA pursuant to 21 C.F.R. Part 312, and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the Respondent and the FDA related thereto. The term “Application” also includes any submissions or applications to the EMA that are similar in content or purpose to the above-described applications to the FDA.

J. “Array” means Array BioPharma Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware with its headquarters address located at 3200 Walnut Street, Boulder, Colorado 80301.

K. “Array License Agreement” means the *License Agreement* by and between Novartis International Pharmaceutical Ltd. and

W. "Contract Manufacture Product(s)" means:

1. the Oncology Products; and
2. any ingredient, material, or component held exclusively for the use for the manufacture of the foregoing Products including the active pharmaceutical ingredient, excipients or packaging materials.

X. "Development" means all preclinical and clinical drug development activities (including formulation), including test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, conducting Clinical Trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Product (including any government price or reimbursement approvals), Product Approval(s) and registration, and regulatory affairs related to the foregoing. "Develop" means to engage in Development.

Y. "Direct Cost" means a cost not to exceed the cost of labor, material, travel and other expenditures to the extent the costs are directly incurred to provide the relevant assistance or service. "Direct Cost" to the Acquirer for its use of any of the Respondent's employees' labor shall not exceed the average hourly wage rate for such employee; *provided, however,* ut nPh c e . r c e

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Asset Transfer Agreement) (related to Encorafenib, *i.e.*, LGX818);

15. The *Transition Agreement* by and between Novartis Pharma AG and Array BioPharma to be executed as of the Effective Date (as that term is defined in the *LGX818 Asset Transfer Agreement*) (related to Encorafenib, *i.e.*, LGX818);

16. The *Amended and Restated Three-Way Clinical Trial Agreement* by and between Array BioPharma Inc., and Novartis Pharma AG to be executed as of the Effective Date (as that term is defined in the *LGX818 Asset Transfer Agreement*) (related to Encorafenib, *i.e.*, LGX818 and to Binimetinib, *i.e.*, MEK 162);

17. The *Amended and Restated Columbus Trial Agreement* by and between Novartis

3. any Manufacturing Designee(s), Clinical Trial Research Organization Designee(s), licensees, sublicensees, manufacturers, suppliers, distributors, and customers of that Acquirer, or of such Acquirer-

2. pursuant to which the Respondent had or has as of the Closing Date the ability to independently purchase the active pharmaceutical ingredient(s) or had planned to purchase the active pharmaceutical ingredient(s) from any Third Party for use in connection with the manufacture of such Oncology Product(s);

3. pursuant to which the Respondent had or has as of the Closing Date the ability to independently purchase necessary ingredients or components other than the active pharmaceutical ingredient(s) or had planned to purchase such necessary ingredients or components from any Third Party for use in connection with the manufacture of such Oncology Product(s) other than such ingredients or components as are widely available for purchase and use in pharmaceutical preparations;

4. relating to any Clinical Trials involving such Oncology Product(s);

5. with universities or other research institutions for the use of such Oncology Product(s) in scientific research;

6. relating to the particularized marketing of such Oncology Product(s) or educational matters relating solely to that Oncology Product(s);

7. pursuant to which a Third Party manufactures such Oncology Product(s) on behalf of the Respondent;

8. pursuant to which a Third Party provides any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging oturn 4.s-10(y)20(P)-h pusu h instit

provided, however, that, where any such contract or agreement also relates to a Retained Product(s), the Respondent shall (i) provide to that Acquirer the benefits of use of such contract or agreement (ii) partially assign to that Acquirer or otherwise divide such contract or agreement into one contract or agreement for Acquirer and one contract or agreement for Respondent, and/or (iii) enable that Acquirer to obtain alternative benefits independently.

YY. "Product Copyrights" means rights to all original works of authorship of any kind directly related to the specified Product and any registrations and applications for registrations thereof within the Geographic Territory, including, but not limited to, the

b. job title or position held;

c. a specific description of the employee's responsibilities related to the Oncology Product; *provided, however*, that, in lieu of this description, the Respondent may provide the employee's most recent performance appraisal;

d. the base salary or current wages;

e. the most recent bonus paid, aggregate annual compensation for the Respondent's last fiscal year and current target or guaranteed bonus, if any;

f. employment status (*i.e.*, active or on leave or disability; full-time or part-time);

g.

CCC. "Product Licensed Intellectual Property" means the following:

1. Patents that are related to an Oncology Product that the Respondent can demonstrate have been used, prior to the Acquisition Date, for any Retained Product that is the subject of an active (not discontinued) Application as of the Acquisition Date;

2. trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information, and all rights in the Geographic Territory to limit the use or disclosure thereof, that are related to an Oncology Product and that the Respondent can demonstrate have been used, prior to the Acquisition Date, for any Retained Product that is the subject of an active (not discontinued)

4. campaign experience reports; and,

5. list of all equipment used to manufacture a product.

FFF. "Product Marketing Materials" means all marketing materials specifically related to the specified Product and used, or intended for use in the marketing or sale of the specified Product in the Geographic Territory as of the Closing Date, including, without limitation, all advertising materials, training materials, product data, mailing lists, sales materials (*e.g.*, detailing reports, vendor lists, sales data), marketing information (*e.g.*, competitor information, research data, market intelligence reports, statistical programs (if any) used for marketing and sales research), customer information (including customer net purchase information to be provided on the basis of either dollars and/or units for each month, quarter or year), sales forecasting models, educational materials, and advertising and display materials, speaker lists, promotional and marketing materials, Website content and advertising and display materials, artwork for the production of packaging components, television masters and other similar materials related to the specified Product.

GGG. "Product Research and Development Employees" means all salaried employees of the Respondent who have directly participated in the research, Development, regulatory approval process, or clinical studies of the Oncology Product(s) being acquired by a particular Acquirer (irrespective of the portion of working time involved, unless such participation consisted solely of oversight of legal, accounting, tax or financial compliance) within the twelve (12) month period immediately prior to the Closing Date.

HHH. "Product Scientific and Regulatory Material" means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory and Clinical Trial materials and information.

III. "Product Trade Dress" means the current trade dress of a Product, including, but not limited to, Product packaging, and the lettering of the Product trade name or brand name.

provided, however, Respondent may satisfy this requirement by certifying that that Acquirer has executed all such agreements directly with each of the relevant Third Parties.

E. Respondent shall:

1. submit to each Acquirer, at Respondent's expense, all Confidential Business Information related to the Oncology Product(s) being acquired by that Acquirer;
2. deliver all Confidential Business Information to that Acquirer:
    a. in good faith;
    b. in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and
    c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;
3. pending complete delivery of all such Confidential Business Information to that Acquirer, upon reasonable written notice and request, provide that Acquirer and the Interim Monitor (if any has been appointed) with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Oncology Products being acquired by that Acquirer that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Order;
4. not use, directly or indirectly, any Confidential Business Information that is exclusively related to the Oncology Products other than as necessary to comply with the following:
    a. the requirements of this Order;
    b. Respondent's obligations to the Acquirer under the terms of any applicable Remedial Agreement; or
    c. applicable Law;
5. not disclose or convey any Confidential Business Information that is exclusively related to the Oncology Products, directly or indirectly, to any Person except (i) the Acquirer of the particular Oncology Product(s), (ii) Persons specifically authorized by that Acquirer to receive such information (including, without limitation, those employees of the Respondent authorized to receive such information), (iii) the Commission, (iv) the Interim Monitor (if any has been appointed); or (v) Government Entities that have

6. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information that is exclusively related to the particular research and Development (including, without limitation, the ongoing Clinical Trials) of each respeofctive Oncology Ph[lprdugct

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G. For each Acquirer, Respondent shall:

1. upon reasonable written notice and request from an Acquirer to the Respondent, Contract Manufacture and deliver, or cause to be manufactured and delivered, to the requesting Acquirer, in a timely manner and under reasonable terms and conditions, a supply of each of the Contract Manufacture Products at Supply Cost, for a period of time sufficient to allow that Acquirer (or the Man

4. promptly advise the Acquirer, the Interim Monitor and the Commission in the event material supply issues arise or appear likely to arise;

5. make representations and warranties to the Acquirer being supplied by the Respondent that the Respondent shall hold harmless and indemnify that Acquirer for any liabilities or loss of profits resulting from the failure of the Contract Manufacture Products to be delivered in a timely manner as required by the Remedial Agreement(s) unless the Respondent can demonstrate that the failure was in no part the result of negligence or willful misconduct by the Respondent;

   provided, however, that in each instance where: (i) an agreement to divest relevant assets or Contract Manufacture is specifically referenced and attached to this Order and (ii) such agreement becomes a Remedial Agreement for an Oncology Product, each such agreement may contain limits on the Respondent's aggregate liability for such a failure;

6. during the term of any agreement to Contract Manufacture, upon written request of the Acquirer or the Interim Monitor (if any has been appointed), make available to that Acquirer and the Interim Monitor (if any has been appointed) all records that are available to the Respondent that relate directly to the manufacture of the applicable Contract Manufacture Products that are generated or created after the Closing Date; directly to the manufactialdir

with cGMP, independently of Respondent; (ii) the date the Acquirer of a particular Oncology Product notifies the Commission and Respondent of its intention to abandon its efforts to manufacture such Oncology Product; (iii) the date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the Acquirer of a particular Oncology Product has abandoned its efforts to manufacture such Oncology Product, or (iv) the date thirty (30) months from the Closing Date.

H. Respondent shall require, as a condition of continued employment post-divestiture of the Divestiture Product Assets, that:

1. each employee who has or may have had access to Confidential Business Information sign a confidentiality agreement pursuant to which that employee shall be required to maintain all Confidential Business Information as strictly confidential, including the nondisclosure of that information to all other employees,

J. Respondent shall:

K. Until Respondent completes the divestitures required by this Order and fully provides, or causes to be provided, the Product Manufacturing Technology related to a particular Oncology Product(s) to the Acquirer and transfers the Clinical Trials related to a particular Oncology Product(s) to the Acquirer,

1. Respondent shall take actions as are necessary to:

    a. maintain the full economic viability and marketability of the Businesses related to that Oncology Product;

    b. minimize any risk of loss of competitive potential for that Business;

    c. prevent the destruction, removal, wasting, deterioration, or impairment of

5. provide, in a timely manner, assistance and advice to enable the Acquirer and/or its Clinical Research Organization Designee(s) to continue such Clinical Trial in its phase as of the Closing Date in the same quality, scope, and pace as was being achieved by the Respondent and in a manner consistent with Good Clinical Practices.

M. Respondent shall not join, file, prosecute or maintain any suit, in law or equity, against an Acquirer or the Oncology Product Releasee(s) of the Acquirer under the following:

1. any Patent owned by or licensed to the Respondent as of the day after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof;

2. any Patent that was filed or in existence on or before the Acquisition Date that is acquired by or licensed to the Respondent at any time after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof;

if such suit would have the potential directly to limit or interfere with the Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Oncology Product(s) acquired by that Acquirer for the purposes of marketing, sale or offer for sale within the United States of America of such Oncology Product(s); or (ii) the use within, import into, export from, or the supply, distribution, or sale within, the United States of America of Oncology Product(s) acquired by that Acquirer. Respondent shall also covenant to the Acquirer that, as a condition of any assignment or license from the Respondent to a Third Party of the above-described Patents, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue the Acquirer or the related Oncology Product Releasee(s) under such Patents, if the suit would have the potential directly to limit or interfere with the Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Oncology Product(s) acquired by that Acquirer for the purposes of marketing, sale or offer for sale within the United States of America of such Oncology Product(s); or (ii) the use within, import into, export from, or the supply, distribution, or sale or offer for sale within, the United States of America of the Oncology Product(s) acquired by that Acquirer. The provisions of this Paragraph do not apply to any Patent owned by, acquired by or licensed to or from the Respondent that claims inventions conceived by and reduced to practice after the Acquisition Date.

notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture that Oncology Product;

Oncology Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent.

I. Respondent may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.

J. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.

K. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph.

L. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.

M. The Interim Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

IV.

IT IS FURTHER ORDERED that:

A. If Respondent has not fully complied with the obligations to assign, grant, license, divest, transfer, deliver or otherwise convey either the B-Raf Inhibitor Assets or the MEK Inhibitor Assets as required by this Order, the Commission may appoint a trustee ("Divestiture Trustee") to assign, grant, license, divest, transfer, deliver or otherwise convey these assets, as applicable, in a manner that satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an action pursuant to § 5(*l*) of the Federal Trade Commission Act, 15 U.S.C. § 45(*l*), or any other statute enforced by the Commission, Respondent shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(*l*) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondent to comply with this Order.

the manner and to an Acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondent from among those approved by the Commission; *provided further, however*, that Respondent shall select such Person within five (5) days after receiving notification of the Commission's approval.

5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondent, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondent, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondent, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

6. Respondent shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not

E. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.

VI.

IT IS FURTHER ORDERED that:

A. Any Remedial Agreement shall be deemed incorporated into this Order.

B. Any failure by the Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.

C. Respondent shall include in each Remedial Agreement related to each of the Oncology Product(s) a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of each Respondent's obligation to the Acquirer pursuant to this Order.

D. Respondent shall not seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to any of the Oncology Products a decision the result of which would be inconsistent with the terms of this Order or the remedial purposes thereof.

E. Unless otherwise determined by the Commission, each of the Oncology Product Divestiture Agreements shall become a Remedial Agreement on the Order Date.

F. Respondent shall not modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission, except as otherwise provided in Rule 2.41(f)(5) of the Commission's Rules of Practice and Procedure, 16 C.F.R. § 2.41(f)(5). Notwithstanding any term of the Remedial Agreement(s), any modification or amendment of any Remedial Agreement made without the prior approval of the Commission, or as otherwise provided in Rule 2.41(f)(5), shall constitute a failure to comply with this Order.

VII.

IT IS FURTHER ORDERED that:

A. Within five (5) days of the Acquisition, Respondent shall submit to the Commission a letter certifying the date on which the Acquisition occurred.

B. Within thirty (30) days after the Order Date, and every sixty (60) days thereafter until Respondent has fully complied with Paragraphs II.A., II.B., II.C., II.D., II.E.1, II.E.2, II.E.3, II.E.7., II.F., II.G. II.H., II.I. and II.J., Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order. Respondent shall submit at the same time a copy of its report concerning compliance with this Order to the Interim Monitor, if any Interim Monitor has been appointed. Respondent shall include in its reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant paragraphs of the Order, including:

1. a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and rights, (ii) transitional services being provided by the Respondent to the Acquirer, and (iii) the agreement(s) to Contract Manufacture; and

2. a detailed description of the timing for the completion of such obligations.

C. Respondent shall notify the Commission prior to consenting to and/or entering into any agreement with, and/or proposing any remedial or other action from, any non-U.S. Government Entity that might have the effect of causing the Respondent and/or the Acquirer to sell or otherwise dispose of, any assets or intellectual property related to the Oncology Products that relate to countries outside of the United States of America. Respondent shall include in such notification, among other things that might be required by staff of the Commission, a full description of all substantive contacts or negotiations related to the sale or disposal of such assets and/or intellectual property rights and the identity of all Persons contacted, including copies of all written communications to and from such Persons, all internal memoranda, and all reports and recommendations concerning the sale and/or disposal of such assets and/or intellectual property rights.

D. One (1) year after the Order Date, annually for the next nine years on the anniversary of the Order Date, and at other times as the Commission may require, Respondent shall file a verified written report with the Commission setting forth in detail the manner and form in which it has complied and is complying with the Order.

VIII.

IT IS FURTHER ORDERED F

A. access, during business office hours of the Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of

NON-PUBLIC APPENDIX I
ONCOLOGY PRODUCT DIVESTITURE AGREEMENTS

[Redacted From the Public Record Version, But Incorporated By Reference]

NON-PUBLIC APPENDIX II
OTHER AGREEMENTS RELATED TO