UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CASE NO. 20-cr-538

UNITED STATES OF AMERICA

v.

NOVARTIS HELLAS S.A.C.I.

Defendant.

_____/

DEFERRED PROSECUTION AGREEMENT

Defendant Novartis Hellas S.A.C.I. ("Novartis Hellas" or the "Company"), pursuant to the authority granted by the Company's Board of Directors reflected in Attachment B, which is incorporated by reference into this Agreement, and the United States Department of Justice, Criminal Division, Fraud Section (the "Fraud Section") and the United States Attorney's Office for the District of New Jersey (the "Office"), enter into this deferred prosecution agreement (the "Agreement"). Novartis AG, which is not a defendant in this matter, also agrees, pursuant to the authority granted by Novartis AG's Board of Directors, to certain terms and obligations of the Agreement as described below. The terms and conditions of this Agreement are as follows:

Criminal Information and Acceptance of Responsibility

1. The Company acknowledges and agrees that the Fraud Section and the Office will file the attached two-count criminal Information (the "Information") in the United States District Court for the District of New Jersey charging the Company with one count of conspiracy to commit an offense against the United States, in violation of Title 18, United States Code, Section 371, that

is, to violate the anti-bribery provisions of the Foreign Corrupt Practices Act of 1977 ("FCPA"), as amended, Title 15, United States Code, Section 78dd-3, and one count of conspiracy to commit an offense against the United States, in violation of Title 18, United States Code, Section 371, that is, to violate the books and records provision of the FCPA, as amended, Title 15, United States Code, Sections 78m(b)(2)(A), 78m(b)(5), and 78ff(a). In so doing, the Company: (a) knowingly waives its right to indictment on these charges, as well as all rights to a speedy trial pursuant to the Sixth Amendment to the United States Constitution, Title 18, United States Code, Section 3161, and Federal Rule of Criminal Procedure 48(b); and (b) knowingly waives any objection with respect to venue to any charges by the United States arising out of the conduct described in the Statement of Facts attached as Attachment A (the "Statement of Facts"), which is incorporated into this Agreement, and consents to the filing of the Information, as provided under the terms of this Agreement, in the United States District Court for the District of New Jersey. The Fraud Section and the Office agree to defer prosecution of the Company pursuant to the terms and conditions described below.

2. The Company admits, accepts, and acknowledges that it is responsible under United States law for the acts of its officers, directors, employees, and agents as charged in the Information, and as set forth in the Statement of Facts, and that the allegations described in the Information and the facts described in the Statement of Facts are true and accurate. Should the Fraud Section or the Office pursue the prosecution that is deferred by this Agreement, the Company and Novartis AG stipulate to the admissibility of the attached Statement of Facts in any proceeding by the Fraud Section or the Office, including any trial, guilty plea, or sentencing proceeding, and will not contradict anything in the Statement of Facts at any such proceeding.

Term of the Agreement

3. This Agreement is effective for a period beginning on the date on which the Information is filed and ending three years from that date (the "Term"). The Company, and the parent company, Novartis AG, agree, however, that, in the event the Fraud Section and the Office determine, in their sole discretion, that the Company or Novartis AG has knowingly violated any provision of this Agreement or has failed to completely perform or fulfill each of the Company's or Novartis AG's obligations under this Agreement, an extension or extensions of the Term of the Agreement may be imposed by the Fraud Section and the Office, in their sole discretion, for up to a total additional time period of one year, without prejudice to the Fraud Section's or the Office's right to proceed as provided in Paragraphs 14 to 18 below. Any extension of the Agreement extends all terms of this Agreement, including the terms of the reporting requirement in Attachment D (the "Reporting Requirements"), for an equivalent period. Conversely, in the event the Fraud Section and the Office find, in their sole discretion, that there exists a change in circumstances sufficient to eliminate the Reporting Requirements, and that the other provisions of this Agreement have been satisfied, the Agreement may be terminated early. If the Court rejects the Agreement, all the provisions of the Agreement shall be deemed null and void, and the Term shall be deemed to have not begun.

Relevant Considerations

4. The Fraud Section and the Office enter into this Agreement based on the individual facts and circumstances presented by this case and by the Company and Novartis AG, including:

a. the Company did not receive voluntary disclosure credit pursuant to the

FCPA Corporate Enforcement Policy in the Department of Justice Manual 9-47.120, or pursuant to the United States Sentencing Guidelines ("U.S.S.G." or "Sentencing Guidelines"), because it did not voluntarily self-disclose to the Fraud Section and the Office the conduct described in the attached Statement of Facts;

b. the Company received full credit for its cooperation and Novartis AG's cooperation with the Fraud Section's and the Office's investigation, including conducting a thorough internal investigation; making regular factual presentations to the Fraud Section and the Office; producing extensive documentation, including documents located outside of the United States, after taking steps that the Company and its affiliates determined complied with applicable foreign data privacy, confidentiality, and discovery laws; and providing translations of foreign language documents;

c. the Company and Novartis AG engaged in remedial measures, including implementing revised and enhanced policies and procedures relating to, among other things, accounting, anti-corruption, gifts, travel, and entertainment, both globally and at the country level; enhancing controls relating to sponsorships to international medical congresses and Phase IV studies; and working with outside counsel to conduct an extensive internal investigation of the Company's operations in Greece;

d. the Company and Novartis AG have committed to continuing to enhance their compliance programs and internal controls, including ensuring that their compliance programs satisfy the minimum elements set forth in Attachment C to the Agreement (the "Corporate Compliance Program");

e. based on the Company's and Novartis AG's remediation and the state of their compliance programs, and the Company's and Novartis AG's agreement to report to the Fraud Section and the Office as set forth in the Reporting Requirements, the Fraud Section and the Office determined that an independent compliance monitor is unnecessary;

f. Novartis AG, the Company's parent company, has resolved with the United States Securities and Exchange Commission (the "SEC") through a cease-and-desist proceeding relating to the conduct described in the attached Statement of Facts and other conduct, and has agreed to pay $92,300,000 in disgorgement and prejudgment interest of $20,500,000;

g. the nature and seriousness of the offense conduct, as described in the Statement of Facts, including payments made in connection with the sponsorship of health care providers ("HCPs") employed by public institutions in Greece to attend international congresses as a means to bribe and corruptly influence the HCPs to increase prescriptions of a Novartis-branded drug and the falsification of books, records, and accounts to conceal payments related to improper benefits and things of value and other improper payments to HCPs, as well as the duration of the misconduct and the involvement of high-level sales and business unit employees at the Company;

h. Novartis AG's March 2016 resolution of FCPA accounting allegations relating to similar conduct in China with the SEC;

i. the Company has agreed to continue to cooperate with the Fraud Section and the Office in any ongoing investigation as described in Paragraph 5 below;

j. Accordingly, after considering (a) through (i) above, the Company received full cooperation and remediation credit, but because Novartis AG was involved in similar conduct

for which it reached a resolution with the SEC in March 2016, the 25 percent reduction for cooperation and remediation was deducted from a point above the midpoint of the applicable Sentencing Guidelines fine range.

Future Cooperation and Disclosure Requirements

5. The Company shall cooperate fully with the Fraud Section and the Office in any and all matters relating to the conduct described in this Agreement and the attached Statement of Facts and other conduct under investigation by the Fraud Section and the Office at any time during the Term, subject to applicable laws and regulations, until the later of the date upon which all investigations and prosecutions arising out of such conduct are concluded, or the end of the Term. At the request of the Fraud Section and the Office, the Company shall also cooperate fully with other domestic or foreign law enforcement and regulatory authorities and agencies, as well as the Multilateral Development Banks (the "MDBs"), in any investigation of the Company or any of its subsidiaries or affiliates, or any of its present or former officers, directors, employees, agents, and consultants, or any other party, in any and all matters relating to the conduct described in this Agreement and the attached Statement of Facts and other conduct under investigation by the Fraud Section and the Office. The Company's cooperation pursuant to this Paragraph is subject to applicable laws and regulations, including relevant data privacy and national security laws, as well as valid claims of attorney-client privilege or attorney work product doctrine; however, the Company must provide to the Fraud Section and the Office a log of any information or cooperation that is not provided based on an assertion of law, regulation, or privilege, and the Company bears the burden of establishing the validity of any such assertion. The Company agrees that its cooperation pursuant to this Paragraph shall include, but not be limited to, the following:

a. The Company shall truthfully disclose all factual information with respect to its activities, those of its subsidiaries and affiliates, and those of its present and former directors, officers, employees, agents, and consultants, including any evidence or allegations and internal or external investigations, about which the Company has any knowledge or about which the Fraud Section and the Office may inquire. This obligation of truthful disclosure includes, but is not limited to, the obligation of the Company to provide to the Fraud Section and the Office, upon request, any document, record, or other tangible evidence about which the Fraud Section and the Office may inquire of the Company.

b. Upon request of the Fraud Section and the Office, the Company shall designate knowledgeable employees, agents, or attorneys to provide to the Fraud Section and the Office the information and materials described in Paragraph 5(a) above on behalf of the Company. It is further understood that the Company must at all times provide complete, truthful, and accurate information.

c. The Company shall use its best efforts to make available for interviews or testimony, as requested by the Fraud Section and the Office, present or former officers, directors, employees, agents, and consultants of the Company. This obligation includes, but is not limited to, sworn testimony before a federal grand jury or in federal trials, all meetings requested by the Fraud Section and the Office, and interviews with domestic or foreign law enforcement and regulatory authorities. Cooperation under this Paragraph shall include identification of witnesses who, to the knowledge of the Company, may have material information regarding the matters being investigated or prosecuted.

d. With respect to any information, testimony, documents, records, or other tangible evidence provided to the Fraud Section and the Office pursuant to this Agreement, the Company consents to any and all disclosures, subject to applicable laws and regulations, to other governmental authorities, including United States authorities and those of a foreign government, as well as the MDBs, of such materials as the Fraud Section and the Office, in their sole discretion, shall deem appropriate.

6. In addition to the obligations in Paragraph 5, during the Term, should the Company learn of any evidence or allegation of conduct that may constitute a violation of the FCPA anti-bribery or accounting provisions had the conduct occurred within the jurisdiction of the United States, the Company shall promptly report such evidence or allegation to the Fraud Section and the Office.

Payment of Monetary Penalty

7. The Fraud Section, the Office and the Company agree that application of the Sentencing Guidelines to determine the applicable fine range yields the following analysis:

a. The November 1, 2018 version of the U.S.S.G. is applicable to this matter.

b. Offense Level. Based upon U.S.S.G. § 2C1.1, the total offense level is 38, calculated as follows:

(a)(2) Base Offense Level	12
(b)(1) Multiple Bribes	+2
(b)(2) Value of Benefit Received (more than $65,000,000 but not more than $150,000,000)	+24
TOTAL	38

c. Base Fine. Based upon U.S.S.G. § 8C2.4(a)(1) the base fine is $150,000,000

d. Culpability Score. Based upon U.S.S.G. § 8C2.5, the culpability score is 6, calculated as follows:

(a) Base Culpability Score	5
(b)(3) the organization had 200 or more employees and an individual within high-level personnel of the organization participated in, condoned, or was willfully ignorant of the offense	+3
(g)(2) The organization fully cooperated in the investigation and clearly demonstrated recognition and affirmative acceptance of responsibility for its criminal conduct	-2
TOTAL	6

Calculation of Fine Range:

Base Fine	$150,000,000
Multipliers	1.20(min)/2.40(max)
Fine Range	$180,000,000/$360,000,000

The Company agrees to pay a total monetary penalty in the amount of $225,000,000 (the "Total Criminal Fine"). The Total Criminal Fine will be paid to the United States Treasury within ten business days of the execution of this Agreement. The Company, the Fraud Section, and the Office agree that this penalty is appropriate given the facts and circumstances of this case, including the Relevant Considerations described in Paragraph 4 of this Agreement. The Total Criminal Fine is final and shall not be refunded. Furthermore, nothing in this Agreement shall be deemed an agreement by the Fraud Section and the Office that the Total Criminal Fine is the maximum penalty that may be imposed in any future prosecution, and the Fraud Section and the Office are not

precluded from arguing in any future prosecution that the Court should impose a higher fine, although the Fraud Section and the Office agree that under those circumstances, they will recommend to the Court that any amount paid under this Agreement should be offset against any fine the Court imposes as part of a future judgment. The Company acknowledges that no tax deduction may be sought in connection with the payment of any part of the Total Criminal Fine. The Company shall not seek or accept directly or indirectly reimbursement or indemnification from any source with regard to the penalty or disgorgement amounts that the Company pays pursuant to this Agreement or any other agreement entered into with an enforcement authority or regulator, including the SEC, concerning the facts set forth in the attached Statement of Facts, except that the Company may seek reimbursement and indemnification from its parent company, Novartis AG. Novartis AG shall not seek or accept, directly or indirectly, reimbursement or indemnification from any source with regard to the penalty or disgorgement amounts that Novartis AG pays, directly or indirectly, including through reimbursement, to the Company, in association with this Agreement or any other agreement entered into with an enforcement authority or regulator, including the SEC, concerning the facts set forth in the attached Statement of Facts. Novartis AG acknowledges that no tax deduction may be sought in connection with the payment, reimbursement, or indemnification of any part of the Total Criminal Fine in connection with this Agreement or the separate deferred prosecution agreement among the Fraud Section, the Office, and Alcon Pte Ltd, dated on or about June 25, 2020.

Conditional Release from Liability

8. Subject to Paragraphs 14 to 18, the Fraud Section and the Office agree, except as provided in this Agreement, that they will not bring any criminal or civil case against the Company,

Novartis AG, or any of their subsidiaries or affiliates, relating to any of the conduct described in the Statement of Facts or the Information filed pursuant to this Agreement. The Fraud Section and the Office, however, may use any information related to the conduct described in the Statement of Facts against the Company, Novartis AG, or any of their subsidiaries or affiliates: (a) in a prosecution for perjury or obstruction of justice; (b) in a prosecution for making a false statement; (c) in a prosecution or other proceeding relating to any crime of violence; or (d) in a prosecution or other proceeding relating to a violation of any provision of Title 26 of the United States Code.

a. This Agreement does not provide any protection against prosecution for any future conduct by the Company, Novartis AG, or any of their subsidiaries or affiliates.

b. In addition, this Agreement does not provide any protection against prosecution of any individuals, regardless of their affiliation with the Company, Novartis AG, or any of their subsidiaries or affiliates.

Corporate Compliance Program

9. The Company and Novartis AG represent that they have implemented and will continue to implement a compliance and ethics program designed to prevent and detect violations of the FCPA and other applicable anti-corruption laws throughout their operations, including those of their affiliates, agents, and joint ventures, and those of their contractors and subcontractors whose responsibilities include interacting with foreign officials or other activities carrying a high risk of corruption, including, but not limited to, the minimum elements set forth in Attachment C.

10. In order to address any deficiencies in their internal accounting controls, policies, and procedures, the Company and Novartis AG represent that they have undertaken, and will continue to undertake in the future, in a manner consistent with all of their obligations under this

Agreement, a review of their existing internal accounting controls, policies, and procedures, regarding compliance with the FCPA and other applicable anti-corruption laws. Where necessary and appropriate, the Company and Novartis AG agree to modify their existing compliance programs, including internal controls, compliance policies, and procedures in order to ensure that they maintain: (a) an effective system of internal accounting controls designed to ensure the making and keeping of fair and accurate books, records, and accounts; and (b) a rigorous anti-corruption compliance program that incorporates relevant internal accounting controls, as well as policies and procedures designed to effectively detect and deter violations of the FCPA and other applicable anti-corruption laws. The compliance programs, including the internal accounting controls systems, will include, but not be limited to, the minimum elements set forth in Attachment C.

Corporate Compliance Reporting

11. Novartis AG agrees that it will report to the Fraud Section and the Office annually during the Term regarding remediation and implementation of the compliance measures described in Attachment C. These reports will be prepared in accordance with Attachment D.

Deferred Prosecution

12. In consideration of the undertakings agreed to by the Company and Novartis AG herein, the Fraud Section and the Office agree that any prosecution of the Company for the conduct set forth in the attached Statement of Facts be and is hereby deferred for the Term. To the extent that there is conduct disclosed by the Company or Novartis AG that is not set forth in the attached Statement of Facts, such conduct will not be exempt from further prosecution and is not within the scope of or relevant to this Agreement.

13. The Fraud Section and the Office further agree that if the Company and Novartis AG fully comply with all of their obligations under this Agreement, the Fraud Section and the Office will not continue the criminal prosecution against the Company described in Paragraph 1 and, at the conclusion of the Term, this Agreement shall expire. Within six months of the Agreement's expiration, the Fraud Section and the Office shall seek dismissal with prejudice of the Information filed against the Company described in Paragraph 1, and agree not to file charges in the future against the Company, Novartis AG, or any of their subsidiaries or affiliates based on the conduct described in this Agreement and the attached Statement of Facts.

Breach of the Agreement

14. If, during the Term: (a) the Company commits any felony under U.S. federal law; (b) the Company or Novartis AG provides in connection with this Agreement deliberately false, incomplete, or misleading information, including in connection with its disclosure of information about individual culpability; (c) the Company fails to cooperate as set forth in Paragraphs 5 and 6 of this Agreement; (d) the Company or Novartis AG fails to implement a compliance program as set forth in Paragraphs 9 and 10 of this Agreement and Attachment C; (e) the Company commits any act that, had it occurred within the jurisdictional reach of the FCPA, would be a violation of the FCPA; or (f) the Company or Novartis AG otherwise fails to completely perform or fulfill each of the Company's and Novartis AG's obligations under the Agreement, regardless of whether the Fraud Section and the Office become aware of such a breach after the Term is complete, the Company, Novartis AG, and their subsidiaries and affiliates, shall thereafter be subject to prosecution for any federal criminal violation of which the Fraud Section and the Office have knowledge, including, but not limited to, the charges in the Information described in Paragraph 1,

which may be pursued by the Fraud Section and the Office in the United States District Court for the District of New Jersey or any other appropriate venue. Determination of whether the Company or Novartis AG has breached the Agreement and whether to pursue prosecution of the Company, Novartis AG, or their subsidiaries or affiliates, shall be in the Fraud Section's and the Office's sole discretion. Any such prosecution may be premised on information provided by the Company, Novartis AG, their subsidiaries or affiliates, or their personnel. Any such prosecution relating to the conduct described in the Statement of Facts or relating to conduct known to the Fraud Section and the Office prior to the date on which this Agreement was signed that is not time-barred by the applicable statute of limitations on the date of the signing of this Agreement may be commenced against the Company, Novartis AG, or their subsidiaries or affiliates, notwithstanding the expiration of the statute of limitations, between the signing of this Agreement and the expiration of the Term plus one year. Thus, by signing this Agreement, the Company and Novartis AG agree that the statute of limitations with respect to any such prosecution that is not time-barred on the date of the signing of this Agreement shall be tolled for the Term plus one year. In addition, the Company agrees that the statute of limitations as to any violation of federal law that occurs during the Term will be tolled from the date upon which the violation occurs until the earlier of the date upon which the Fraud Section and the Office are made aware of the violation or the duration of the Term plus five years, and that this period shall be excluded from any calculation of time for purposes of the application of the statute of limitations.

15. In the event the Fraud Section and the Office determine that the Company or Novartis AG has breached this Agreement, the Fraud Section and the Office agree to provide the Company and Novartis AG with written notice of such breach prior to instituting any prosecution

resulting from such breach. Within thirty days of receipt of such notice, the Company and Novartis AG shall have the opportunity to respond to the Fraud Section and the Office in writing to explain the nature and circumstances of such breach, as well as the actions the Company and Novartis AG have taken to address and remediate the situation, which explanation the Fraud Section and the Office shall consider in determining whether to pursue prosecution of the Company, Novartis AG, or their subsidiaries or affiliates.

16. In the event the Fraud Section and the Office determine that the Company or Novartis AG has breached this Agreement: (a) all statements made by or on behalf of the Company Novartis AG, or their subsidiaries or affiliates to the Fraud Section and the Office or to the Court, including the attached Statement of Facts, and any testimony given by the Company, Novartis AG, or their subsidiaries or affiliates before a grand jury, a court, or any tribunal, or at any legislative hearings, whether prior or subsequent to this Agreement, and any leads derived from such statements or testimony, shall be admissible in evidence in any and all criminal proceedings brought by the Fraud Section and the Office against the Company, Novartis AG, or their subsidiaries or affiliates; and (b) the Company, Novartis AG, or their subsidiaries or affiliates shall not assert any claim under the United States Constitution, Rule 11(f) of the Federal Rules of Criminal Procedure, Rule 410 of the Federal Rules of Evidence, or any other federal rule that any such statements or testimony made by or on behalf of the Company, Novartis AG, or their subsidiaries or affiliates prior or subsequent to this Agreement, or any leads derived therefrom, should be suppressed or are otherwise inadmissible. The decision whether conduct or statements of any current director, officer, or employee, or any person acting on behalf of, or at the direction of, the Company, Novartis AG, or their subsidiaries or affiliates will be imputed to the Company

or Novartis AG for the purpose of determining whether the Company or Novartis AG has violated any provision of this Agreement shall be in the sole discretion of the Fraud Section and the Office.

17. The Company and Novartis AG acknowledge that the Fraud Section and the Office have made no representations, assurances, or promises concerning what sentence may be imposed by the Court if the Company or Novartis AG breaches this Agreement and this matter proceeds to judgment. The Company and Novartis AG further acknowledge that any such sentence is solely within the discretion of the Court and that nothing in this Agreement binds or restricts the Court in the exercise of such discretion.

18. On the date that the period of deferred prosecution specified in this Agreement expires, the Company, by the Chief Executive Officer of the Company and the Chief Financial Officer of the Company, will certify to the Fraud Section and the Office that the Company has met its disclosure obligations pursuant to Paragraphs 5 and 6 of this Agreement. Each certification will be deemed a material statement and representation by the Company to the executive branch of the United States for purposes of Title 18, United States Code, Sections 1001 and 1519, and it will be deemed to have been made in the judicial district in which this Agreement is filed.

Sale, Merger, or Other Change in Corporate Form of the Company

19. Except as may otherwise be agreed by the parties in connection with a particular transaction, the Company and Novartis AG agree that in the event that, during the Term, the Company or Novartis AG undertake any change in corporate form, including if it sells, merges, or transfers business operations that are material to the Company's or Novartis AG's consolidated operations, or to the operations of any subsidiaries or affiliates involved in the conduct described in the attached Statement of Facts, as they exist as of the date of this Agreement, whether such

change is structured as a sale, asset sale, merger, transfer, or other change in corporate form, it shall include in any contract for sale, merger, transfer, or other change in corporate form a provision binding the purchaser, or any successor in interest thereto, to the obligations described in this Agreement. The purchaser or successor in interest must also agree in writing that the Fraud Section's and the Office's ability to declare a breach under this Agreement is applicable in full force to that entity. The Company and Novartis AG agree that the failure to include these provisions in the transaction will make any such transaction null and void. The Company and Novartis AG shall provide notice to the Fraud Section and the Office at least thirty days prior to undertaking any such sale, merger, transfer, or other change in corporate form. The Fraud Section and the Office shall notify the Company and Novartis AG prior to such transaction (or series of transactions) if they determine that the transaction(s) will have the effect of circumventing or frustrating the enforcement purposes of this Agreement. At any time during the Term the Company or Novartis AG engages in a transaction(s) that has the effect of circumventing or frustrating the enforcement purposes of this Agreement, the Fraud Section and the Office may deem it a breach of this Agreement pursuant to Paragraphs 14 to 18 of this Agreement. Nothing herein shall restrict the Company or Novartis AG from indemnifying (or otherwise holding harmless) the purchaser or successor in interest for penalties or other costs arising from any conduct that may have occurred prior to the date of the transaction, so long as such indemnification does not have the effect of circumventing or frustrating the enforcement purposes of this Agreement, as determined by the Fraud Section and the Office.

Public Statements by the Company and Novartis AG

20. The Company and Novartis AG expressly agree that they shall not, through present or future attorneys, officers, directors, employees, agents or any other person authorized to speak for the Company or Novartis AG, make any public statement, in litigation or otherwise, contradicting the acceptance of responsibility by the Company or Novartis AG set forth above or the facts described in the attached Statement of Facts. Any such contradictory statement shall, subject to cure rights of the Company and Novartis AG described below, constitute a breach of this Agreement, and the Company and/or Novartis AG thereafter shall be subject to prosecution as set forth in Paragraphs 14 to 16 of this Agreement. The decision whether any public statement by any such person contradicting a fact contained in the attached Statement of Facts will be imputed to the Company and/or Novartis AG for the purpose of determining whether it has breached this Agreement shall be at the sole discretion of the Fraud Section and the Office. If the Fraud Section and the Office determine that a public statement by any such person contradicts in whole or in part a statement contained in the attached Statement of Facts, the Fraud Section and the Office shall so notify the Company and Novartis AG, and the Company and Novartis AG may avoid a breach of this Agreement by publicly repudiating such statement(s) within five business days after notification. The Company and Novartis AG shall be permitted to raise defenses and to assert affirmative claims in other proceedings relating to the matters set forth in the attached Statement of Facts provided that such defenses and claims do not contradict, in whole or in part, a statement contained in the attached Statement of Facts. This Paragraph does not apply to any statement made by any present or former officer, director, employee, or agent of the Company or

Novartis AG in the course of any criminal, regulatory, or civil case initiated against such individual, unless such individual is speaking on behalf of the Company and/or Novartis AG.

21. The Company and Novartis AG agree that if they or any of their direct or indirect subsidiaries or affiliates issue a press release or hold any press conference in connection with this Agreement, the Company and Novartis AG shall first consult with the Fraud Section and the Office to determine: (a) whether the text of the release or proposed statements at the press conference are true and accurate with respect to matters between the Fraud Section, the Office, the Company, and Novartis AG; and (b) whether the Fraud Section and the Office have any objection to the release or statement.

22. The Fraud Section and the Office agree, if requested to do so, to bring to the attention of law enforcement and regulatory authorities the facts and circumstances relating to the nature of the conduct underlying this Agreement, including the nature and quality of the Company's and Novartis AG's cooperation and remediation. By agreeing to provide this information to such authorities, the Fraud Section and the Office are not agreeing to advocate on behalf of the Company, Novartis AG, or their subsidiaries or affiliates, but rather are agreeing to provide facts to be evaluated independently by such authorities. Nothing in this Agreement restricts in any way the ability of the Fraud Section and the Office, any other federal department or agency, or any state or local government, from proceeding criminally, civilly, or administratively, against any current or former directors, officers, employees, or agents of the Company, Novartis AG, its subsidiaries or affiliates, or against any other entities or individuals. The parties to this Agreement intend that the Agreement does not confer or provide any benefits, privileges, immunities, or rights to any other individual or entity other than the parties hereto.

Limitations on Binding Effect of the Agreement

23. This Agreement is binding on the Company, Novartis AG, the Fraud Section, and the Office, but specifically does not bind any other component of the Department of Justice, other federal agencies, or any state, local, or foreign law enforcement or regulatory agencies, or any other authorities, although the Fraud Section and the Office will bring the cooperation of the Company and Novartis AG and their compliance with their other obligations under this Agreement to the attention of such agencies and authorities if requested to do so by the Company or Novartis AG.

Notice

24. Any notice to the Fraud Section and the Office under this Agreement shall be given by personal delivery, overnight delivery by a recognized delivery service, or registered or certified mail, addressed to Chief, FCPA Unit, Fraud Section, Criminal Division, U.S. Department of Justice, 1400 New York Avenue, NW, 11th Floor, Washington, D.C. 20530, and Chief, Health Care Fraud Unit, United States Attorney's Office for the District of New Jersey, 970 Broad Street, 7th Floor, Newark, New Jersey 07102. Any notice to the Company and Novartis AG under this Agreement shall be given by personal delivery, overnight delivery by a recognized delivery service, or registered or certified mail, addressed to Novartis AG, Group General Counsel, Novartis Campus / Asklepios 8.14, 4002 Basel, Switzerland; Novartis Hellas S.A.C.I., Office of the President and CEO, Metamorphosis P.O. Box 144 51, 12th klm. National Road No. 1, Athens, Greece; and Charles E. Duross, Morrison & Foerster LLP, 2000 Pennsylvania Avenue, NW, Washington, D.C. 20006, or by electronic mail to those individuals or to other counsel or individuals identified to the Fraud Section and the Office by the Company and/or Novartis AG.

Notice shall be effective upon actual receipt by the Fraud Section and the Office or the Company and Novartis AG.

Complete Agreement

25. This Agreement, including its attachments, sets forth all the terms of the agreement between the Company, Novartis AG, the Fraud Section, and the Office. No amendments, modifications or additions to this Agreement shall be valid unless they are in writing and signed by the Fraud Section and the Office, the attorneys for the Company and Novartis AG, and a duly authorized representative of the Company and Novartis AG.

AGREED:

FOR NOVARTIS HELLAS S.A.C.I.:

Date: 23/6/2020

By: _____
Susanne Kohout
President and Chief Executive Officer
Novartis Hellas S.A.C.I.

Novartis Hellas S.A.C.I.
A Novartis Pharmaceutical company
12th klm. National Road No1
Metamorphosis P.O. Box 144 51
Tax Id: 094022290 / FAE Athens

Date: 6/23/2020

By: _____
Charles E. Duross
James M. Koukios
Demme Doufekias
Morrison & Foerster LLP
Counsel for Novartis Hellas S.A.C.I.

FOR NOVARTIS AG:

Date: _____

By: _____
Shannon Thyme Klinger
Group General Counsel

Date: _____

By: _____
Harry Kirsch
Chief Financial Officer

Date: _____

By: _____
Charles E. Duross
James M. Koukios
Demme Doufekias
Morrison & Foerster LLP
Counsel for Novartis AG

AGREED:

FOR NOVARTIS HELLAS S.A.C.I.:

Date: _____ By: _____

Susanne Kohout
President and Chief Executive Officer
Novartis Hellas S.A.C.I.

Date: _____ By: _____

Charles E. Duross
James M. Koukios
Demme Doufekias
Morrison & Foerster LLP
Counsel for Novartis Hellas S.A.C.I.

FOR NOVARTIS AG:

Date: 23 June 2020 By: _____

Shannon Thyme Klinger
Group General Counsel

Date: 23 June 2020 By: _____

Harry Kirsch
Chief Financial Officer

Date: 6/23/2020 By: _____

Charles E. Duross
James M. Koukios
Demme Doufekias
Morrison & Foerster LLP
Counsel for Novartis AG

FOR THE DEPARTMENT OF JUSTICE:

ROBERT A. ZINK
Chief, Fraud Section
Criminal Division
United States Department of Justice

Date: 06/25/2020

BY: _____
Della Sentilles
Trial Attorney

CRAIG CARPENITO
United States Attorney
District of New Jersey

Date: 6/25/2020

BY: _____
Bernard J. Cooney
Senior Trial Counsel
Joshua L. Haber
Assistant United States Attorney

COMPANY OFFICER'S CERTIFICATE

I have read this Agreement and carefully reviewed every part of it with outside counsel for Novartis Hellas S.A.C.I. (the "Company"). I understand the terms of this Agreement and voluntarily agree, on behalf of the Company, to each of its terms. Before signing this Agreement, I consulted outside counsel for the Company. Counsel fully advised me of the rights of the Company, of possible defenses, of the provisions of the U.S. Sentencing Guidelines, and of the consequences of entering into this Agreement.

I have carefully reviewed the terms of this Agreement with the Board of Directors of the Company. I have caused outside counsel for the Company to advise the Board of Directors fully of the rights of the Company, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into the Agreement.

No promises or inducements have been made other than those contained in this Agreement. Furthermore, no one has threatened or forced me, or to my knowledge any person authorizing this Agreement on behalf of the Company, in any way to enter into this Agreement. I am also satisfied with outside counsel's representation in this matter. I certify that I am the President and Chief Executive Officer of the Company and that I have been duly authorized by the Company to execute this Agreement on behalf of the Company.

Date: 23/6/2020

Novartis Hellas S.A.C.I.

By: _____

Susanne Kohout
President and Chief Executive Officer

Novartis (Hellas) S.A.C.I.
Pharmaceutical company
12th km. National Road No1
Metamorphosis P.O. Box 144 51
Tax id: 094021290 / FAE Athens

CERTIFICATE OF COUNSEL

I am counsel for Novartis Hellas S.A.C.I. (the "Company") in the matter covered by this Agreement. In connection with such representation, I have examined relevant Company documents and have discussed the terms of this Agreement with the Company's Board of Directors. Based on our review of the foregoing materials and discussions, I am of the opinion that the representative of the Company has been duly authorized to enter into this Agreement on behalf of the Company and that this Agreement has been duly and validly authorized, executed, and delivered on behalf of the Company and is a valid and binding obligation of the Company. Further, I have carefully reviewed the terms of this Agreement with the Board of Directors and the President and Chief Executive Officer of the Company. I have fully advised them of the rights of the Company, of possible defenses, of the provisions of the U.S. Sentencing Guidelines, and of the consequences of entering into this Agreement. To my knowledge, the decision of the Company to enter into this Agreement, based on the authorization of the Board of Directors and a relevant resolution of the Company's General Shareholders Meeting, is an informed and voluntary one.

Date: June 23, 2020

By: _____

James M. Koukios
Morrison & Foerster LLP
Counsel for Novartis Hellas S.A.C.I.

NOVARTIS AG OFFICER'S CERTIFICATE

I have read this Agreement and carefully reviewed every part of it with outside counsel for Novartis AG. I understand the terms of this Agreement and voluntarily agree, on behalf of Novartis AG, to each of its terms. Before signing this Agreement, I consulted outside counsel for Novartis AG. Counsel fully advised me of the rights of Novartis AG, of possible defenses, of the provisions of the U.S. Sentencing Guidelines, and of the consequences of entering into this Agreement.

I have carefully reviewed the terms of this Agreement with the Board of Directors of Novartis AG. I have advised the Board of Directors fully of the rights of Novartis AG, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into the Agreement.

No promises or inducements have been made other than those contained in this Agreement. Furthermore, no one has threatened or forced me, or to my knowledge any person authorizing this Agreement on behalf of Novartis AG, in any way to enter into this Agreement. I am also satisfied with outside counsel's representation in this matter. I certify that I am the Group General Counsel for Novartis and that, together with another authorized signatory, I am duly authorized by Novartis AG to execute this Agreement on behalf of Novartis AG.

Date: 23 JUNE 2020

Novartis AG

By: _____

Shannon Thyme Klinger
Group General Counsel

CERTIFICATE OF COUNSEL

I am counsel for Novartis AG in the matter covered by this Agreement. In connection with such representation, I have examined relevant Novartis AG documents and have discussed the terms of this Agreement with the Group General Counsel for Novartis. Based on our review of the foregoing materials and discussions, and on my discussions with the Group General Counsel, I am of the opinion that the representatives of Novartis AG are duly authorized to enter into this Agreement on behalf of Novartis AG and that this Agreement has been duly and validly authorized, executed, and delivered on behalf of Novartis AG and is a valid and binding obligation of Novartis AG. Further, I have fully advised the Group General Counsel of the rights of Novartis AG, of possible defenses, of the provisions of the U.S. Sentencing Guidelines, and of the consequences of entering into this Agreement. To my knowledge, and based on my discussions with the Group General Counsel, the decision of Novartis AG to enter into this Agreement, based on the authorization of the Board of Directors, is an informed and voluntary one.

Date: 6/23/2020

By: _____
Charles E. Duross
Morrison & Foerster LLP
Counsel for Novartis AG

ATTACHMENT A

STATEMENT OF FACTS

The following Statement of Facts is incorporated as part of the Deferred Prosecution Agreement (the "Agreement") between the United States Department of Justice, Criminal Division, Fraud Section (the "Fraud Section"), the United States Attorney's Office for the District of New Jersey (the "Office"), and Novartis Hellas S.A.C.I. ("Novartis Hellas" or the "Company"). The Company agrees and stipulates that the following facts and conclusions of U.S. law are true and accurate. The Company admits, accepts, and acknowledges that it is responsible for the acts of its officers, directors, employees, and agents as set forth below. Should the Fraud Section and the Office pursue the prosecution that is deferred by this Agreement, the Company agrees that it will neither contest the admissibility of, nor contradict, this Statement of Facts in any such proceeding. The following facts took place during the relevant time period and establish beyond a reasonable doubt the charges set forth in the Information attached to this Agreement:

Relevant Entities and Individuals

1. The Company was a Greek corporation headquartered in Athens, Greece and a wholly-owned subsidiary of Novartis AG, a global pharmaceutical company based in Basel, Switzerland. Among other lines of business, the Company sold and marketed Novartis-branded prescription drugs in Greece. Novartis AG's American Depository Shares were listed and traded on the New York Stock Exchange under the symbol "NVS." Novartis AG was an issuer of publicly traded securities registered pursuant to Section 12(b) of the Securities Exchange Act and was required to file periodic reports with the United States Securities and Exchange Commission (the "SEC") under Section 13 of the Securities Exchange Act. Thus, Novartis AG was an "issuer"

within the meaning of the Foreign Corrupt Practices Act ("FCPA"), 15 U.S.C. §§ 78dd-1(a) and 78m(b). The Company's books, records, and accounts were included in the consolidated financial statements of Novartis AG filed with the SEC.

2. "Novartis Hellas Employee 1," an individual whose identity is known to the Fraud Section and the Office, was a manager at the Company between in or about January 2011 and in or about 2015.

3. "Novartis Hellas Employee 2," an individual whose identity is known to the Fraud Section and the Office, held various positions at the Company between in or about 2012 and in or about 2015.

The Greek Health Care System, Greek Entities, and Foreign Officials

4. Greece owned and operated state-owned and state-controlled hospitals and clinics, and these hospitals and clinics performed a state function. Individuals employed by these hospitals and clinics were "foreign officials" within the meaning of the FCPA, 15 U.S.C. § 78dd-3(f)(2)(A).

5. "Greek State-Owned Clinic," an entity whose identity is known to the Fraud Section and the Office, was a state-owned and state-controlled medical clinic located in Athens, Greece that performed functions that Greece treated as its own, and thus was an instrumentality within the meaning of the FCPA, 15 U.S.C. § 78dd-3(f)(2)(A).

6. "Greek HCP 1," an individual whose identity is known to the Fraud Section and the Office, was a health care provider ("HCP"), an employee of Greek State-Owned Clinic, and a "foreign official" within the meaning of the FCPA, 15 U.S.C. § 78dd-3(f)(2)(A).

Overview of the Unlawful Schemes

7. During the relevant time periods set forth below, the Company, through its employees and agents, knowingly and willfully conspired and agreed to corruptly provide improper benefits and things of value to employees of state-owned and state-controlled hospitals and clinics in Greece ("Greek State HCPs") and other HCPs in Greece with the intent to obtain an improper advantage and to increase sales of a certain Novartis-branded prescription drug in Greece. Specifically, the Company sponsored Greek State HCPs to attend international congresses as a means to bribe and corruptly influence the HCPs to increase prescriptions of Lucentis.[1]

8. During the relevant time periods set forth below, the Company, through its employees and agents, also knowingly and willfully conspired and agreed to cause certain payments to be falsely recorded in Novartis AG's books, records, and accounts. Specifically, the Company falsely recorded as legitimate advertising and promotion expenses: (a) corrupt payments related to the international congresses described above; and (b) improper payments to HCPs related to an epidemiological study intended to increase sales of certain Novartis-branded prescription drugs. These records were consolidated into Novartis AG's financial records and used to support Novartis AG's financial reporting to the SEC. As such, the Company, through its employees and agents, caused these payments to be falsely recorded in Novartis AG's books, records, and accounts.

[1] Lucentis was a prescription drug sold by the Company in Greece that is approved for several indications, including to treat adults with neovascular (wet) age-related macular degeneration.

9. During this time period, the Company recognized at least $71.48 USD million in profits, as calculated for the purposes of the U.S. Sentencing Guidelines, from sales of Lucentis in Greece and from sales of Novartis-branded prescription drugs related to the epidemiological study.

Details of the International Medical Congress Scheme

10. Between in or about 2012 and in or about 2015, the Company paid for public and private ophthalmologists in Greece to attend international "medical congresses." These congresses were organized by various medical associations in the United States and Europe, and typically took place over several days in a destination city in the United States or Europe.

11. By sponsoring Greek State HCPs to attend congresses, the Company paid for the costs associated with that Greek State HCP's attendance, such as airfare, hotel accommodations, and congress registration fees. The Company typically paid for travel costs associated with congresses through third-party travel agencies. For each individual Greek State HCP, the total cost to the Company for attendance of an international congress often exceeded $6,000 USD.

12. The Company's policies stated that the purpose for sending HCPs to congresses was to provide scientific or educational information. In reality, however, sales employees at the Company, including Novartis Hellas Employee 1, sometimes used international congresses to improperly influence and induce Greek State HCPs to increase prescriptions for Lucentis.

13. As part of the scheme, the Company maintained internal documentation noting that HCPs with the highest potential and highest propensity to prescribe Lucentis would receive "investments," such as sponsorships to attend international congresses, while HCPs with lower potential and less propensity to prescribe Lucentis would receive no such "investments."

14. The use of congresses as a means to improperly influence and induce Greek State HCPs to prescribe Lucentis was discussed and documented at the Company. For example, on or about September 27, 2012, the Company's Lucentis Brand Team held a meeting to discuss the sales strategy for Greek State HCPs. Among other attendees, Novartis Hellas Employee 1 and Novartis Hellas Employee 2 participated in the meeting. In the written minutes from this meeting (the "Minutes"), a section entitled "Increase Pressure in [*sic*] HCPs" reflected the Company's intent to use specific international congress sponsorships to corruptly influence Greek State HCPs. In particular, the Minutes stated that Greek State HCPs "must understand that their participation in [specific congresses in the United States and Europe] will be cancelled if sales performance is not improved significantly."

15. The Minutes further explained that the Company's message that it would withdraw its international congress sponsorships based on poor Lucentis sales performance "must also be discussed with [sales] REPs in the next Sales team [meeting]. REPs must make clear to their [HCP] customers that Lucentis is facing real difficulties in the market and for this reason there will be serious consequences."

16. The Minutes referred to a certain U.S.-based ophthalmology association that organized a congress in the U.S. (the "U.S. Academy"). Sales employees in the Company's ophthalmology business unit sent selected HCPs, including Greek State HCPs, to the U.S. Academy's congress, and employees of the Company traveled to the United States and, while located in the United States, facilitated the attendance of the Greek State HCPs at the U.S. Academy's congress, as a method to corruptly influence the HCPs.

17. In or around January 2013, Novartis Hellas Employee 1 prepared a presentation entitled "Action Plan KOLs" which detailed the various means through which Novartis Hellas Employee 1 and others at the Company intended to target various "Top KOLs," or Key Opinion Leaders, in ophthalmology (the "Action Plans").

18. One such Action Plan targeted Greek HCP 1, who worked at the Greek State-Owned Clinic. The Action Plan set forth how Novartis Hellas Employee 1 and others at the Company intended to use certain "actions"—including sponsorship to U.S. congresses—to induce Greek HCP 1 to prescribe Lucentis. The "Target" was to "increase" Greek HCP 1's "loyalty" to the Company and "chan[ge] [HCP 1's] mindset about cooperation." As described in the Action Plan's "Strategy-Actions" section, Novartis Hellas Employee 1 and others at the Company sought to achieve this objective through, among other "actions," "tak[ing] advantage of [the U.S. Academy's] congresses."

19. The Action Plan further stated that Novartis Hellas Employee 1 and others at the Company should convey the following message to Greek HCP 1: "to get you must write. No presents anymore."

20. The Action Plan indicated that Novartis Hellas Employee 1 would "ASK HIM ALL," meaning that the goal was to capture 100% of Greek HCP 1's ophthalmology prescriptions for which Lucentis could be prescribed.

21. In or about late 2013, employees of the Company traveled to the United States and, while located in the United States, facilitated the attendance of Greek HCP 1 and others at the U.S. Academy's congress in New Orleans, Louisiana.

22. In addition to Greek HCP 1, an Action Plan written by Novartis Hellas Employee 1 stated that the Company's ophthalmology business unit would "[l]ower investment [in another Greek State HCP] as a penalty for [Lucentis injection] loss" while making their "motive (large investment)" visible to the HCP. To generate increased Lucentis prescriptions from one particular Greek State HCP, another Action Plan written by Novartis Hellas Employee 1 stated that the "Implementation Plan" consisted of specific European congresses and the U.S. Academy's congress along with a reference to "5500 grand [*sic*] for congress."

23. In or about 2013, certain employees in the Company's ophthalmology business unit developed a plan that outlined the various "activities" they intended to use to influence HCPs at a public hospital's ophthalmology clinic (the "Greek Hospital Clinic"). These activities included "Participation in Congress (4x INTL, 10x National)."

24. In or about 2014, Novartis Hellas Employee 1 and another manager at the Company wrote a basketball-themed written presentation for the Company's Lucentis brand team (the "Presentation"). The Presentation addressed how the Company's Lucentis brand team should approach Greek State HCPs who preferred a competitor company's product and who raised certain "defenses" against using Lucentis. Among other "defenses," these HCPs indicated that the competitor company's products were the preferred choice to treat age-related macular degeneration and were less expensive. The Presentation described how the Company intended to overcome these "defenses" through the use of improper inducements to "convert" Greek State HCPs to prescribing Lucentis.

25. One "defense," which was described against the backdrop of an image of a world famous basketball player's face on a dollar bill, stated (as translated): "[the competitor company]

has a large budget to invest 'they told me, whatever you want.'" The competitor company's strategy, as indicted in the Presentation, included sending Greek State HCPs to U.S. congresses.

26. The Presentation further explained how the Company sought to "dissolve" this "defense" through, among other things, sending targeted Greek State HCPs to ophthalmology congresses in Europe and the United States. This included sending ten HCPs to the U.S. Academy's congress at a cost of 67,000 euros (equivalent to then approximately $89,000 USD).

27. The Company, through its employees and agents, falsely recorded the corrupt payments associated with congress sponsorships as legitimate advertising and promotion expenses in the Company's internal accounting records. By recording these payments as advertising and promotion expenses, the Company concealed their true and corrupt nature. These false records were consolidated into Novartis AG's financial records and used to support Novartis AG's financial reporting to the SEC. As such, the Company, through its employees and agents, knowingly and willfully conspired and agreed with others to cause the corrupt payments to be falsely recorded as legitimate expenses in Novartis AG's books, records, and accounts.

Details of the Clinical Trial Scheme

Background on Clinical Trials at the Company

28. The Company was not responsible for Phase I, II, or III clinical trials, which relate to different phases of the process leading from a drug's discovery to government approval. However, the Company sponsored post-approval clinical trials, known as Phase IV studies and epidemiological studies, both of which were research studies intended to answer scientific questions related to medical conditions treated by Novartis-branded prescription drugs. In this

role, and depending on the study, the Company selected Greek public and private HCPs to gather patient data for the studies.

29. Phase IV studies and epidemiological studies were designed to inform medical and clinical decisions, not to increase sales. As set forth below, however, the Company made improper payments to HCPs related to an epidemiological study intended to increase sales of certain Novartis-branded prescription drugs.

The EXACTLY Study

30. In or about 2008, employees of the Company responsible for marketing Novartis-branded hypertension prescription drugs developed a marketing project named "EXACTLY." The brand managers prepared a written "Project Summary" for EXACTLY dated November 19, 2008 (the "Project Summary"). According to the Project Summary, the Company planned to provide HCPs with free blood pressure manometers and the HCPs would provide the Company with information related to their patients, including uncontrolled or newly diagnosed patients with hypertension. Through EXACTLY, the Company sought to increase sales of Novartis-branded hypertension prescription drugs.

31. The Project Summary described including over 2,200 HCPs who, in turn, treated over 44,000 patients. With an anticipated return on investment ("ROI") of 3.04, the planned investment of over 2.8 million euros (equivalent to then approximately $3.8 million USD) in payments to HCPs through EXACTLY was expected to yield sales of over 8.6 million euros (the equivalent to then approximately $11.9 million USD). This projected ROI, the Project Summary explained, included over 16,000 "newly diagnosed or uncontrolled patients."

32. On or about November 19, 2008, the Project Summary for EXACTLY was submitted to the Company's Country Compliance Board ("CCB") for internal approval. As reflected in the CCB's Program Review Meeting Minutes from on or about November 19, 2008, the CCB deemed EXACTLY to be "of high value," but decided that all or part of the project should be converted to a "Scientific Investigation." The CCB made this decision, in part, because EXACTLY involved collecting patient data and would thus require approval from the Greek government's National Organization for Medicines (Ethnikos Organismos Farmakon) (the "Greek EOF").

33. The Company accordingly redesigned a portion of EXACTLY as an epidemiological investigational study designed "to evaluate the percentage of uncontrolled hypertensive patients" in Greece. Instead of providing free manometers to HCPs, the investigational study version of EXACTLY entailed the Company paying participating HCPs directly. Participating HCPs were responsible for gathering patient data and completing case report forms to record data for each enrolled patient.

34. In or about February 2009, the Greek EOF approved EXACTLY as an investigational study.

35. From in or about April 2009 through in or about December 2009, the Company and HCPs conducted the EXACTLY study which was designed to target over 2,200 HCPs and over 44,000 patients.

36. Ultimately, the Company, through its employees and agents, made improper payments to HCPs.

37. Many of the forms that were submitted contained mistakes and inconsistencies, including forms that failed to indicate whether the patient suffered from coronary disease, which is strongly linked to hypertension — the core purported focus of EXACTLY.

38. The Company's employees also recognized that many HCPs believed that they were paid in exchange for writing prescriptions for Novartis-branded hypertension prescription drugs and not for providing data as part of a clinical study. Specifically, on or about April 15, 2010, the Company held an internal meeting for brand managers and other personnel involved with EXACTLY "to summarize the learnings and identify next steps" (the "EXACTLY Debrief"). During the EXACTLY Debrief, which the Company audio recorded, regarding payments that HCPs received related to EXACTLY, a number of employees and managers acknowledged the following:

- A Company manager stated that (as translated): "[A]lthough the microphone is recording . . . you all know this very well, I just repeat, that the doctor believes that he/she participates in a study [EXACTLY] and gets paid for what he prescribes in reality and not for what he/she writes in the study. . . Consequently, the doctor's impression was that they participate just so that they get paid for what they prescribe."

- A Company sales manager stated (as translated): "[T]he main issue is . . . that the doctors believe that the study was conducted in order to get paid for what they write, right?"

- A Company medical manager stated (as translated) that a clinical study "is a part of the marketing mix; we do not disagree that this is a type of benefit provided to the doctors. They know that they will get paid, this is what happens in reality."

- A Company brand manager stated that (as translated): "To be honest, the studies were conducted in a similar way in the past as well; they were conducted as marketing projects. That's within quotation marks. Between us."

39. The Company, through its employees and agents, falsely recorded these payments related to EXACTLY as advertising and promotion expenses in the Company's internal accounting

records. By doing so, the Company concealed their true and improper nature. These false records were consolidated into Novartis AG's financial records and were used to support Novartis AG's financial reporting to the SEC. As such, the Company, through its employees and agents, knowingly and willfully conspired and agreed with others to cause the payments related to EXACTLY to be falsely recorded as legitimate expenses in Novartis AG's books, records, and accounts.

ATTACHMENT B

CERTIFIED MINUTES OF THE BOARD OF DIRECTORS FOR NOVARTIS HELLAS S.A.C.I.

WHEREAS, Novartis Hellas S.A.C.I. (the "Company") has been engaged in discussions with the United States Department of Justice, Criminal Division, Fraud Section (the "Fraud Section") and the United States Attorney's Office for the District of New Jersey (the "Office") regarding issues arising in relation to improper payments made in connection with providing benefits and things of value to health care providers ("HCPs") in Greece, including HCPs employed by Greek public institutions, and the falsification of books, records, and accounts to conceal those improper payments, benefits, and things of value; and

WHEREAS, in order to resolve such discussions, it is proposed that the Company enter into a certain agreement with the Fraud Section and the Office in accordance with the relevant resolution of the General Shareholders; and

WHEREAS, the Company's inside counsel, together with outside counsel for the Company, has advised the Board of Directors of the Company of its rights, possible defenses, the provisions of the U.S. Sentencing Guidelines, and the consequences of entering into such agreement with the Fraud Section and the Office;

Therefore, the Board of Directors has RESOLVED that:

1. The Company: (a) acknowledges the filing of the Information charging the Company with one count of conspiracy to commit an offense against the United States, in violation of Title 18, United States Code, Section 371, that is, to violate the anti-bribery provisions of the Foreign Corrupt Practices Act of 1977 ("FCPA"), as amended, Title 15, United States Code, Section 78dd-3, and one count of conspiracy to commit an offense against the United States, in

violation of Title 18, United States Code, Section 371, that is, to violate the books and records provision of the FCPA, as amended, Title 15, United States Code, Sections 78m(b)(2)(A), 78m(b)(5), and 78ff(a); (b) waives indictment on such charges and enters into a deferred prosecution agreement with the Fraud Section and the Office (the "Agreement"); and (c) agrees to accept a monetary penalty against the Company with respect to the conduct described in the Information totaling $225,000,000, and to pay such penalty to the United States Treasury within ten business days of the execution of the Agreement;

2. The Company accepts the terms and conditions of this Agreement, including, but not limited to: (a) a knowing waiver of its rights to a speedy trial pursuant to the Sixth Amendment to the United States Constitution, Title 18, United States Code, Section 3161, and Federal Rule of Criminal Procedure 48(b); (b) a knowing waiver for purposes of this Agreement and any charges by the United States arising out of the conduct described in the attached Statement of Facts of any objection with respect to venue and consents to the filing of the Information, as provided under the terms of this Agreement, in the United States District Court for the District of New Jersey; and (c) a knowing waiver of any defenses based on the statute of limitations for any prosecution relating to the conduct described in the attached Statement of Facts, or relating to conduct known to the Fraud Section and the Office prior to the date on which this Agreement was signed, that is not time-barred by the applicable statute of limitations on the date of the signing of this Agreement;

3. The Chairman and Chief Executive Officer of the Company, Susanne Kohout, is hereby authorized, empowered, and directed, on behalf of the Company, to execute the Agreement substantially in such form as reviewed by this Board of Directors at this meeting with such changes as the President and Chief Executive Officer of the Company may approve;

4. The Chairman and Chief Executive Officer of the Company, Susanne Kohout, is hereby authorized, empowered, and directed to take any and all actions as may be necessary or appropriate and to approve the forms, terms or provisions of any agreement or other documents as may be necessary or appropriate, to carry out and effectuate the purpose and intent of the foregoing resolutions; and

5. All of the actions of the Chairman and Chief Executive Officer of the Company, Susanne Kohout, which would have been authorized by the foregoing resolutions except that such actions were taken prior to the adoption of such resolutions, are hereby severally ratified, confirmed, approved, and adopted as actions on behalf of the Company.

Date: 23/6/2020

By: _____

Susanne Kohout
Chairman and Chief Executive Officer
Novartis Hellas S.A.C.I.

Novartis (Hellas) S.A.C.I.
Pharmaceutical company
12th klm. National Road No1
Metamorphosis P.O. Box 144 51
Tax id: 094021290 / FAE Athens

CERTIFICATE OF CORPORATE RESOLUTIONS FOR NOVARTIS AG

WHEREAS, Novartis AG has been engaged in discussions with the United States Department of Justice, Criminal Division, Fraud Section (the "Fraud Section") and the United States Attorney's Office for the District of New Jersey (the "Office") regarding issues arising in relation to improper payments made in connection with providing benefits and things of value to health care providers ("HCPs") in Greece, including HCPs employed by Greek public institutions, and the falsification of books, records, and accounts to conceal those improper payments, benefits, and things of value; and

WHEREAS, in order to resolve such discussions, it is proposed that Novartis AG (on behalf of itself and its subsidiaries and affiliates) agrees to certain terms and obligations of a deferred prosecution agreement among Novartis Hellas S.A.C.I. ("Novartis Hellas"), the Fraud Section, and the Office (the "Agreement"); and

WHEREAS, the Group General Counsel for Novartis, Shannon Thyme Klinger, has advised the Board of Directors of Novartis AG of its rights, possible defenses, the Sentencing Guidelines' provisions, and the consequences of agreeing to such terms and obligations of the Agreement among Novartis Hellas, the Fraud Section, and the Office;

Therefore, the Board of Directors has RESOLVED that:

1. Novartis AG: (a) acknowledges the filing of the Information against its subsidiary, Novartis Hellas, charging Novartis Hellas with one count of conspiracy to commit an offense against the United States, in violation of Title 18, United States Code, Section 371, that is, to violate the anti-bribery provisions of the Foreign Corrupt Practices Act of 1977 ("FCPA"), as amended, Title 15, United States Code, Section 78dd-3, and one count of conspiracy to commit an

offense against the United States, in violation of Title 18, United States Code, Section 371, that is, to violate the books and records provision of the FCPA, as amended, Title 15, United States Code, Sections 78m(b)(2)(A), 78m(b)(5), and 78ff(a); (b) undertakes certain obligations under the Agreement among Novartis Hellas, the Fraud Section, and the Office; and (c) agrees to accept a monetary penalty against Novartis Hellas totaling $225,000,000, and to pay such penalty to the United States Treasury with respect to the conduct described in the Information if Novartis Hellas does not pay such monetary penalty within the time period specified in the Agreement;

2. Novartis AG accepts the terms and conditions of this Agreement, including, but not limited to: (a) a knowing waiver of Novartis Hellas' right to a speedy trial pursuant to the Sixth Amendment to the United States Constitution, Title 18, United States Code, Section 3161, and Federal Rule of Criminal Procedure 48(b); (b) a knowing waiver for purposes of this Agreement and any charges by the United States arising out of the conduct described in the attached Statement of Facts of any objection with respect to venue and consents to the filing of the Information against Novartis Hellas, as provided under the terms of this Agreement, in the United States District Court for the District of New Jersey; and (c) a knowing waiver of any defenses based on the statute of limitations for any prosecution relating to the conduct described in the attached Statement of Facts, or relating to conduct known to the Fraud Section and the Office prior to the date on which this Agreement was signed, that is not time-barred by the applicable statute of limitations on the date of the signing of this Agreement;

3. The Group General Counsel for Novartis, Shannon Thyme Klinger, together with another authorized signatory, are hereby authorized, empowered, and directed, on behalf of Novartis AG and its subsidiaries and affiliates, to agree to certain terms and obligations of the

Agreement substantially in such form as reviewed by this Board of Directors at this meeting with such changes as the Group General Counsel, together with another authorized signatory, may approve;

4. The Group General Counsel for Novartis, Shannon Thyme Klinger, together with another authorized signatory, are hereby authorized, empowered, and directed to take any and all actions as may be necessary or appropriate and to approve the forms, terms or provisions of any agreement or other documents as may be necessary or appropriate to carry out and effectuate the purpose and intent of the foregoing resolutions; and

5. All of the actions of the Group General Counsel for Novartis, Shannon Thyme Klinger, together with another authorized signatory, which would have been authorized by the foregoing resolutions except that such actions were taken prior to the adoption of such resolutions, are hereby severally ratified, confirmed, approved, and adopted as actions on behalf of Novartis AG and its subsidiaries and affiliates.

Date: 23 June 2020

By: J. Reinhardt

Joerg Reinhardt
Chairman of the Board of Directors
Novartis AG

ATTACHMENT C

CORPORATE COMPLIANCE PROGRAM

In order to address any deficiencies in its internal controls, compliance code, policies, and procedures regarding compliance with the Foreign Corrupt Practices Act ("FCPA"), 15 U.S.C. §§ 78dd-1, *et seq.*, and other applicable anti-corruption laws, Novartis AG, on behalf of itself and its subsidiaries and affiliates, agrees to continue to conduct, in a manner consistent with all of its obligations under this Agreement, appropriate reviews of its existing internal controls, policies, and procedures.

Where necessary and appropriate, Novartis AG agrees to adopt new, or to modify its existing compliance programs, including internal controls, compliance policies, and procedures in order to ensure that it maintains: (a) an effective system of internal accounting controls designed to ensure the making and keeping of fair and accurate books, records, and accounts; and (b) a rigorous anti-corruption compliance program that incorporates relevant internal accounting controls, as well as policies and procedures designed to effectively detect and deter violations of the FCPA and other applicable anti-corruption laws. At a minimum, this should include, but not be limited to, the following elements to the extent they are not already part of Novartis AG's existing internal controls, compliance code, policies, and procedures:

High-Level Commitment

1. Novartis AG will ensure that its directors and senior management provide strong, explicit, and visible support and commitment to its corporate policy against violations of the anti-corruption laws and its compliance codes.

Policies and Procedures

2. Novartis AG will develop and promulgate a clearly articulated and visible corporate policy against violations of the FCPA and other applicable foreign law counterparts (collectively, the "anti-corruption laws"), which policy shall be memorialized in a written compliance code or codes.

3. Novartis AG will develop and promulgate compliance policies and procedures designed to reduce the prospect of violations of the anti-corruption laws and Novartis AG's compliance code, and Novartis AG will take appropriate measures to encourage and support the observance of ethics and compliance policies and procedures against violation of the anti-corruption laws by personnel at all levels of Novartis AG. These anti-corruption policies and procedures shall apply to all directors, officers, and employees and, where necessary and appropriate, outside parties acting on behalf of Novartis AG in a foreign jurisdiction, including, but not limited to, agents and intermediaries, consultants, representatives, distributors, teaming partners, contractors and suppliers, consortia, and joint venture partners (collectively, "agents and business partners"). Novartis AG shall notify all employees that compliance with the policies and procedures is the duty of individuals at all levels of Novartis AG. Such policies and procedures shall address:

a. gifts;

b. hospitality, entertainment, and expenses;

c. customer travel;

d. political contributions;

e. charitable donations and sponsorships;

f. facilitation payments; and

g. solicitation and extortion.

4. Novartis AG will ensure that it has a system of financial and accounting procedures, including a system of internal controls, reasonably designed to ensure the maintenance of fair and accurate books, records, and accounts. This system shall be designed to provide reasonable assurances that:

a. transactions are executed in accordance with management's general or specific authorization;

b. transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles or any other criteria applicable to such statements, and to maintain accountability for assets;

c. access to assets is permitted only in accordance with management's general or specific authorization; and

d. the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

Periodic Risk-Based Review

5. Novartis AG will develop these compliance policies and procedures on the basis of a periodic risk assessment addressing the individual circumstances of Novartis AG, in particular the foreign bribery risks facing Novartis AG, including, but not limited to, its geographical organization, interactions with various types and levels of government officials, industrial sectors of operation, involvement in joint venture arrangements, importance of licenses and permits in

Novartis AG's operations, degree of governmental oversight and inspection, and volume and importance of goods and personnel clearing through customs and immigration.

6. Novartis AG shall review its anti-corruption compliance policies and procedures no less than annually and update them as appropriate to ensure their continued effectiveness, taking into account relevant developments in the field and evolving international and industry standards.

Proper Oversight and Independence

7. Novartis AG will assign responsibility to one or more senior corporate executives of Novartis AG for the implementation and oversight of Novartis AG's anti-corruption compliance code, policies, and procedures. Such corporate official(s) shall have the authority to report directly to independent monitoring bodies, including internal audit, Novartis AG's Board of Directors, or any appropriate committee of the Board of Directors, and shall have an adequate level of autonomy from management as well as sufficient resources and authority to maintain such autonomy.

Training and Guidance

8. Novartis AG will implement mechanisms designed to ensure that its anti-corruption compliance code, policies, and procedures are effectively communicated to all directors, officers, employees, and, where necessary and appropriate, agents and business partners. These mechanisms shall include: (a) periodic training for all directors and officers, all employees in positions of leadership or trust, positions that require such training (e.g., internal audit, sales, legal, compliance, finance), or positions that otherwise pose a corruption risk to Novartis AG, and, where necessary and appropriate, agents and business partners; and (b) corresponding certifications by all such directors, officers, employees, agents, and business partners, certifying compliance with the training requirements.

9. Novartis AG will maintain, or where necessary establish, an effective system for providing guidance and advice to directors, officers, employees, and, where necessary and appropriate, agents and business partners, on complying with Novartis AG's anti-corruption compliance code, policies, and procedures, including when they need advice on an urgent basis or in any foreign jurisdiction in which Novartis AG operates.

Internal Reporting and Investigation

10. Novartis AG will maintain, or where necessary establish, an effective system for internal and, where possible, confidential reporting by, and protection of, directors, officers, employees, and, where appropriate, agents and business partners concerning violations of the anti-corruption laws or Novartis AG's anti-corruption compliance code, policies, and procedures.

11. Novartis AG will maintain, or where necessary establish, an effective and reliable process with sufficient resources for responding to, investigating, and documenting allegations of violations of the anti-corruption laws or Novartis AG's anti-corruption compliance code, policies, and procedures.

Enforcement and Discipline

12. Novartis AG will implement mechanisms designed to effectively enforce its compliance code, policies, and procedures, including appropriately incentivizing compliance and disciplining violations.

13. Novartis AG will institute appropriate disciplinary procedures to address, among other things, violations of the anti-corruption laws and Novartis AG's anti-corruption compliance code, policies, and procedures by Novartis AG's directors, officers, and employees. Such procedures should be applied consistently and fairly, regardless of the position held by, or

perceived importance of, the director, officer, or employee. Novartis AG shall implement procedures to ensure that where misconduct is discovered, reasonable steps are taken to remedy the harm resulting from such misconduct, and to ensure that appropriate steps are taken to prevent further similar misconduct, including assessing the internal controls, compliance code, policies, and procedures and making modifications necessary to ensure the overall anti-corruption compliance program is effective.

Third-Party Relationships

14. Novartis AG will institute appropriate risk-based due diligence and compliance requirements pertaining to the retention and oversight of all agents and business partners, including:

a. properly documented due diligence pertaining to the hiring and appropriate and regular oversight of agents and business partners;

b. informing agents and business partners of Novartis AG's commitment to abiding by anti-corruption laws, and of Novartis AG's anti-corruption compliance code, policies, and procedures; and

c. seeking a reciprocal commitment from agents and business partners.

15. Where necessary and appropriate, Novartis AG will include standard provisions in agreements, contracts, and renewals thereof with all agents and business partners that are reasonably calculated to prevent violations of the anti-corruption laws, which may, depending upon the circumstances, include: (a) anti-corruption representations and undertakings relating to compliance with the anti-corruption laws; (b) rights to conduct audits of the books, records, and accounts of the agent or business partner to ensure compliance with the foregoing; and (c) rights

to terminate an agent or business partner as a result of any breach of the anti-corruption laws, Novartis AG's compliance code, policies, or procedures, or the representations and undertakings related to such matters.

Mergers and Acquisitions

16. Novartis AG will develop and implement policies and procedures for mergers and acquisitions requiring that Novartis AG conduct appropriate risk-based due diligence on potential new business entities, including appropriate FCPA and anti-corruption due diligence by legal, accounting, and compliance personnel.

17. Novartis AG will ensure that Novartis AG's compliance code, policies, and procedures regarding the anti-corruption laws apply as quickly as is practicable to newly acquired businesses or entities merged with Novartis AG and will promptly:

a. train the directors, officers, employees, agents, and business partners consistent with Paragraph 8 above on the anti-corruption laws and Novartis AG's compliance code, policies, and procedures regarding anti-corruption laws; and

b. where warranted, conduct an FCPA-specific audit of all newly acquired or merged businesses as quickly as practicable.

Monitoring and Testing

18. Novartis AG will conduct periodic reviews and testing of its anti-corruption compliance codes, policies, and procedures designed to evaluate and improve their effectiveness in preventing and detecting violations of anti-corruption laws and Novartis AG's anti-corruption codes, policies, and procedures, taking into account relevant developments in the field and evolving international and industry standards.

ATTACHMENT D

REPORTING REQUIREMENTS

Novartis AG agrees that it will report to the Fraud Section and the Office periodically, at no less than twelve-month intervals during a three-year term, regarding remediation and implementation of the compliance program and internal controls, policies, and procedures described in Attachment C. During this three-year period, Novartis AG shall: (1) conduct an initial review and submit an initial report, and (2) conduct and prepare at least two follow-up reviews and reports, as described below:

a. By no later than one year from the date this Agreement is executed, Novartis AG shall submit to the Fraud Section and the Office a written report setting forth a complete description of its remediation efforts to date, its proposals reasonably designed to improve Novartis AG's internal controls, policies, and procedures for ensuring compliance with the FCPA and other applicable anti-corruption laws, and the proposed scope of the subsequent reviews. The report shall be transmitted to Chief, FCPA Unit, Fraud Section, Criminal Division, U.S. Department of Justice, 1400 New York Avenue, NW, Bond Building, 11th Floor, Washington, D.C. 20530 and Chief, Health Care Fraud Unit, United States Attorney's Office for the District of New Jersey, 970 Broad Street, 7th Floor, Newark, New Jersey 07102. Novartis AG may extend the time period for issuance of the report with prior written approval of the Fraud Section and the Office.

b. Novartis AG shall undertake at least two follow-up reviews and reports, incorporating the Fraud Section's and the Office's views on Novartis AG's prior reviews and reports, to further monitor and assess whether Novartis AG's policies and procedures are

reasonably designed to detect and prevent violations of the FCPA and other applicable anti-corruption laws.

c. The first follow-up review and report shall be completed by no later than one year after the initial report is submitted to the Fraud Section and the Office. The second follow-up review and report shall be completed and delivered to the Fraud Section and the Office no later than thirty days before the end of the Term.

d. The reports will likely include proprietary, financial, confidential, and competitive business information. Moreover, public disclosure of the reports could discourage cooperation, impede pending or potential government investigations and thus undermine the objectives of the reporting requirement. For these reasons, among others, the reports and the contents thereof are intended to remain and shall remain non-public, except as otherwise agreed to by the parties in writing, or except to the extent that the Fraud Section and the Office determine in their sole discretion that disclosure would be in furtherance of the Fraud Section's and the Office's discharge of their duties and responsibilities or is otherwise required by law.

e. Novartis AG may extend the time period for submission of any of the follow-up reports with prior written approval of the Fraud Section and the Office.

2017R00136/BJC/JLH

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA	:	Criminal No. 20-538
	:	
v.	:	18 U.S.C. § 371
	:	
NOVARTIS HELLAS S.A.C.I.	:	

INFORMATION

The United States charges that, at all times relevant to this Information, unless otherwise specified:

GENERAL ALLEGATIONS

Relevant Statutory Background

1. The Foreign Corrupt Practices Act of 1977, as amended, 15 U.S.C. §§ 78dd-1, *et seq*. (the "FCPA"), was enacted by Congress for the purpose of, among other things, making it unlawful to act corruptly in furtherance of an offer, promise, authorization, or payment of money or anything of value, directly or indirectly, to a foreign official for the purpose of obtaining or retaining business for, or directing business to, any person. In addition, the FCPA's accounting provisions, among other things, require every issuer of publicly traded securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78l, or required to file periodic reports with the United States Securities and Exchange Commission ("SEC") under Section 15(d) of the Securities Exchange Act, 15 U.S.C § 78o(d), to make and keep books, records, and accounts that accurately and fairly reflect transactions and the distribution of the company's

assets, and prohibit the knowing and willful falsification of an issuer's books, records, or accounts. 15 U.S.C. §§ 78m(b)(2)(A), 78m(b)(5), and 78ff(a).

NOVARTIS HELLAS and Other Relevant Entities and Individuals

2. Defendant Novartis Hellas S.A.C.I. ("NOVARTIS HELLAS") was a Greek corporation headquartered in Athens, Greece and a wholly-owned subsidiary of Novartis AG, a global pharmaceutical company based in Basel, Switzerland. Among other lines of business, NOVARTIS HELLAS sold and marketed Novartis-branded prescription drugs in Greece. Novartis AG's American Depository Shares were listed and traded on the New York Stock Exchange under the symbol "NVS." Novartis AG was an issuer of publicly traded securities registered pursuant to Section 12(b) of the Securities Exchange Act and was required to file periodic reports with the SEC under Section 13 of the Securities Exchange Act. Thus, Novartis AG was an "issuer" within the meaning of the FCPA, 15 U.S.C. §§ 78dd-1(a) and 78m(b). NOVARTIS HELLAS's books, records, and accounts were included in the consolidated financial statements of Novartis AG filed with the SEC.

3. "Novartis Hellas Employee 1," an individual whose identity is known to the United States, was a manager at NOVARTIS HELLAS between in or about January 2011 and in or about 2015.

4. "Novartis Hellas Employee 2," an individual whose identity is known to the United States, held various positions at NOVARTIS HELLAS between in or about 2012 and in or about 2015.

The Greek Health Care System, Greek Entities, and Foreign Officials

5. Greece owned and operated state-owned and state-controlled hospitals and clinics, and these hospitals and clinics performed a state function. Individuals employed by these hospitals and clinics were "foreign officials" within the meaning of the FCPA, 15 U.S.C. § 78dd-3(f)(2)(A).

6. "Greek State-Owned Clinic," an entity whose identity is known to the United States, was a state-owned and state-controlled medical clinic located in Athens, Greece that performed functions that Greece treated as its own, and thus was an instrumentality within the meaning of the FCPA, 15 U.S.C. § 78dd-3(f)(2)(A).

7. "Greek HCP 1," an individual whose identity is known to the United States, was a health care provider ("HCP"), an employee of Greek State-Owned Clinic, and a "foreign official" within the meaning of the FCPA, 15 U.S.C. § 78dd-3(f)(2)(A).

Overview of the Unlawful Schemes

8. During the relevant time periods set forth below, NOVARTIS HELLAS, through its employees and agents, knowingly and willfully conspired and agreed to corruptly provide improper benefits and things of value to employees of state-owned and state-controlled hospitals and clinics in Greece ("Greek State HCPs") and other HCPs in Greece with the intent to obtain an improper advantage and to increase sales of a certain Novartis-branded prescription drug in Greece. Specifically, NOVARTIS HELLAS sponsored Greek

State HCPs to attend international congresses as a means to bribe and corruptly influence the HCPs to increase prescriptions of Lucentis.[1]

9. During the relevant time periods set forth below, NOVARTIS HELLAS, through its employees and agents, also knowingly and willfully conspired and agreed to cause certain payments to be falsely recorded in Novartis AG's books, records, and accounts. Specifically, NOVARTIS HELLAS falsely recorded as legitimate advertising and promotion expenses: (a) corrupt payments related to the international congresses described above; and (b) improper payments to HCPs related to an epidemiological study intended to increase sales of certain Novartis-branded prescription drugs. These records were consolidated into Novartis AG's financial records and used to support Novartis AG's financial reporting to the SEC. As such, NOVARTIS HELLAS, through its employees and agents, caused these payments to be falsely recorded in Novartis AG's books, records, and accounts.

10. During this time period, NOVARTIS HELLAS recognized at least $71.48 million in profits, as calculated for the purposes of the U.S. Sentencing Guidelines, from sales of Lucentis in Greece and from sales of Novartis-branded prescription drugs related to the epidemiological study.

[1] Lucentis was a prescription drug sold by NOVARTIS HELLAS in Greece that is approved for several indications, including to treat adults with neovascular (wet) age-related macular degeneration.

Details of the International Medical Congress Scheme

11. Between in or about 2012 and in or about 2015, NOVARTIS HELLAS paid for public and private ophthalmologists in Greece to attend international "medical congresses." These congresses were organized by various medical associations in the United States and Europe, and typically took place over several days in a destination city in the United States or Europe.

12. By sponsoring Greek State HCPs to attend congresses, NOVARTIS HELLAS paid for the costs associated with that Greek State HCP's attendance, such as airfare, hotel accommodations, and congress registration fees. NOVARTIS HELLAS typically paid for travel costs associated with congresses through third-party travel agencies. For each individual Greek State HCP, the total cost to NOVARTIS HELLAS for attendance of an international congress often exceeded $6,000.

13. NOVARTIS HELLAS's policies stated that the purpose for sending HCPs to congresses was to provide scientific or educational information. In reality, however, sales employees at NOVARTIS HELLAS, including Novartis Hellas Employee 1, sometimes used international congresses to improperly influence and induce Greek State HCPs to increase prescriptions for Lucentis.

14. As part of the scheme, NOVARTIS HELLAS maintained internal documentation noting that HCPs with the highest potential and highest propensity to prescribe Lucentis would receive "investments," such as

sponsorships to attend international congresses, while HCPs with lower potential and less propensity to prescribe Lucentis would receive no such "investments."

15. The use of congresses as a means to improperly influence and induce Greek State HCPs to prescribe Lucentis was discussed and documented at NOVARTIS HELLAS. For example, on or about September 27, 2012, NOVARTIS HELLAS's Lucentis Brand Team held a meeting to discuss the sales strategy for Greek State HCPs. Among other attendees, Novartis Hellas Employee 1 and Novartis Hellas Employee 2 participated in the meeting. In the written minutes from this meeting (the "Minutes"), a section entitled "Increase Pressure in [*sic*] HCPs" reflected NOVARTIS HELLAS's intent to use specific international congress sponsorships to corruptly influence Greek State HCPs. In particular, the Minutes stated that Greek State HCPs "must understand that their participation in [specific congresses in the United States and Europe] will be cancelled if sales performance is not improved significantly."

16. The Minutes further explained that NOVARTIS HELLAS's message that it would withdraw its international congress sponsorships based on poor Lucentis sales performance "must also be discussed with [sales] REPs in the next Sales team [meeting]. REPs must make clear to their [HCP] customers that Lucentis is facing real difficulties in the market and for this reason there will be serious consequences."

17. The Minutes referred to a certain U.S.-based ophthalmology association that organized a congress in the United States (the "U.S. Academy").

Sales employees in NOVARTIS HELLAS's ophthalmology business unit sent selected HCPs, including Greek State HCPs, to the U.S. Academy's congress, and employees of NOVARTIS HELLAS traveled to the United States and, while located in the United States, facilitated the attendance of the Greek State HCPs at the U.S. Academy's congress as a method to corruptly influence the HCPs.

18. In or about January 2013, Novartis Hellas Employee 1 prepared a presentation entitled "Action Plan KOLs" which detailed the various means through which Novartis Hellas Employee 1 and others at NOVARTIS HELLAS intended to target various "Top KOLs," or Key Opinion Leaders, in ophthalmology (the "Action Plans").

19. One such Action Plan targeted Greek HCP 1, who worked at the Greek State-Owned Clinic. The Action Plan set forth how Novartis Hellas Employee 1 and others at NOVARTIS HELLAS intended to use certain "actions"—including sponsorship to U.S. congresses—to induce Greek HCP 1 to prescribe Lucentis. The "Target" was to "increase" Greek HCP 1's "loyalty" to NOVARTIS HELLAS and "chan[ge] [HCP 1's] mindset about cooperation." As described in the Action Plan's "Strategy-Actions" section, Novartis Hellas Employee 1 and others at NOVARTIS HELLAS sought to achieve this objective through, among other "actions," "tak[ing] advantage of [the U.S. Academy's] congresses."

20. The Action Plan further stated that Novartis Hellas Employee 1 and others at NOVARTIS HELLAS should convey the following message to Greek HCP 1: "to get you must write. No presents anymore."

21. The Action Plan indicated that Novartis Hellas Employee 1 would "ASK HIM ALL," meaning that the goal was to capture 100% of Greek HCP 1's ophthalmology prescriptions for which Lucentis could be prescribed.

22. In or about late 2013, employees of NOVARTIS HELLAS traveled to the United States and, while located in the United States, facilitated the attendance of Greek HCP 1 and others at the U.S. Academy's congress in New Orleans, Louisiana.

23. In addition to Greek HCP 1, an Action Plan written by Novartis Hellas Employee 1 stated that NOVARTIS HELLAS's ophthalmology business unit would "[l]ower investment [in another Greek State HCP] as a penalty for [Lucentis injection] loss" while making their "motive (large investment)" visible to the HCP. To generate increased Lucentis prescriptions from one particular Greek State HCP, another Action Plan written by Novartis Hellas Employee 1 stated that the "Implementation Plan" consisted of specific European congresses and the U.S. Academy's congress along with a reference to "5500 grand [*sic*] for congress."

24. In or about 2013, certain employees in NOVARTIS HELLAS's ophthalmology business unit developed a plan that outlined the various "activities" that they intended to use to influence HCPs at a public hospital's

ophthalmology clinic (the "Greek Hospital Clinic"). These activities included "Participation in Congress (4x INTL, 10x National)."

25. In or about 2014, Novartis Hellas Employee 1 and another manager at NOVARTIS HELLAS wrote a basketball-themed written presentation for NOVARTIS HELLAS's Lucentis brand team (the "Presentation"). The Presentation addressed how NOVARTIS HELLAS's Lucentis brand team should approach Greek State HCPs who preferred a competitor company's product and who raised certain "defenses" against using Lucentis. Among other "defenses," these HCPs indicated that the competitor company's products were the preferred choice to treat age-related macular degeneration and were less expensive. The Presentation described how NOVARTIS HELLAS intended to overcome these "defenses" through the use of improper inducements to "convert" Greek State HCPs to prescribing Lucentis.

26. One "defense," which was described against the backdrop of an image of a world famous basketball player's face on a dollar bill, stated (as translated): "[the competitor company] has a large budget to invest 'they told me, whatever you want.'" The competitor company's strategy, as indicated in the Presentation, included sending Greek State HCPs to U.S. congresses.

27. The Presentation further explained how NOVARTIS HELLAS sought to "dissolve" this "defense" through, among other things, sending targeted Greek State HCPs to ophthalmology congresses in Europe and the United States.

This included sending ten HCPs to the U.S. Academy's congress at a cost of 67,000 euros (then equivalent to approximately $89,000).

28. NOVARTIS HELLAS, through its employees and agents, falsely recorded the corrupt payments associated with congress sponsorships as legitimate advertising and promotion expenses in NOVARTIS HELLAS's internal accounting records. By recording these payments as advertising and promotion expenses, NOVARTIS HELLAS concealed their true and corrupt nature. These false records were consolidated into Novartis AG's financial records and used to support Novartis AG's financial reporting to the SEC. As such, NOVARTIS HELLAS, through its employees and agents, knowingly and willfully conspired and agreed with others to cause the corrupt payments to be falsely recorded as legitimate expenses in Novartis AG's books, records, and accounts.

Details of the Clinical Trial Scheme

Background on Clinical Trials at NOVARTIS HELLAS

29. NOVARTIS HELLAS was not responsible for Phase I, II, or III clinical trials, which relate to different phases of the process leading from a drug's discovery to government approval. However, NOVARTIS HELLAS sponsored post-approval clinical trials, known as Phase IV studies and epidemiological studies, both of which were research studies intended to answer scientific questions related to medical conditions treated by Novartis-branded prescription drugs. In this role, and depending on the study, NOVARTIS HELLAS selected Greek public and private HCPs to gather patient data for the studies.

30. Phase IV studies and epidemiological studies were designed to inform medical and clinical decisions, not to increase sales. As set forth below, however, NOVARTIS HELLAS made improper payments to HCPs related to an epidemiological study intended to increase sales of certain Novartis-branded prescription drugs.

The EXACTLY Study

31. In or about 2008, employees of NOVARTIS HELLAS responsible for marketing Novartis-branded hypertension prescription drugs developed a marketing project named "EXACTLY." The brand managers prepared a written "Project Summary" for EXACTLY dated November 19, 2008 (the "Project Summary"). According to the Project Summary, NOVARTIS HELLAS planned to provide HCPs with free blood pressure manometers and the HCPs would provide NOVARTIS HELLAS with information related to their patients, including uncontrolled or newly diagnosed patients with hypertension. Through EXACTLY, NOVARTIS HELLAS sought to increase sales of Novartis-branded hypertension prescription drugs.

32. The Project Summary described including over 2,200 HCPs who, in turn, treated over 44,000 patients. With an anticipated return on investment ("ROI") of 3.04, the planned investment of over 2.8 million euros (equivalent to then approximately $3.8 million) in payments to HCPs through EXACTLY was expected to yield sales of over 8.6 million euros (the equivalent to

then approximately $11.9 million). This projected ROI, the Project Summary explained, included over 16,000 "newly diagnosed or uncontrolled patients."

33. On or about November 19, 2008, the Project Summary for EXACTLY was submitted to NOVARTIS HELLAS's Country Compliance Board ("CCB") for internal approval. As reflected in the CCB's Program Review Meeting Minutes from on or about November 19, 2008, the CCB deemed EXACTLY to be "of high value," but decided that all or part of the project should be converted to a "Scientific Investigation." The CCB made this decision, in part, because EXACTLY involved collecting patient data and would thus require approval from the Greek government's National Organization for Medicines (Ethnikos Organismos Farmakon) (the "Greek EOF").

34. NOVARTIS HELLAS accordingly redesigned a portion of EXACTLY as an epidemiological investigational study designed "to evaluate the percentage of uncontrolled hypertensive patients" in Greece. Instead of providing free manometers to HCPs, the investigational study version of EXACTLY entailed NOVARTIS HELLAS paying participating HCPs directly. Participating HCPs were responsible for gathering patient data and completing case report forms to record data for each enrolled patient.

35. In or about February 2009, the Greek EOF approved EXACTLY as an investigational study.

36. From in or about April 2009 through in or about December 2009, NOVARTIS HELLAS and HCPs conducted the EXACTLY study which was designed to target over 2,200 HCPs and over 44,000 patients.

37. Ultimately, NOVARTIS HELLAS, through its employees and agents, made improper payments to HCPs.

38. Many of the forms that were submitted contained mistakes and inconsistencies, including forms that failed to indicate whether the patient suffered from coronary disease, which is strongly linked to hypertension — the core purported focus of EXACTLY.

39. NOVARTIS HELLAS's employees also recognized that many HCPs believed that they were paid in exchange for writing prescriptions for Novartis-branded hypertension prescription drugs and not for providing data as part of a clinical study. Specifically, on or about April 15, 2010, NOVARTIS HELLAS held an internal meeting for brand managers and other personnel involved with EXACTLY "to summarize the learnings and identify next steps" (the "EXACTLY Debrief"). During the EXACTLY Debrief, which NOVARTIS HELLAS audio recorded, regarding payments that HCPs received related to EXACTLY, a number of employees and managers acknowledged the following:

- A NOVARTIS HELLAS manager stated that (as translated): "[A]lthough the microphone is recording . . . you all know this very well, I just repeat, that the doctor believes that he/she participates in a study [EXACTLY] and gets paid for what he prescribes in reality and not for what he/she writes in the study. . . Consequently, the doctor's impression was that they participate just so that they get paid for what they prescribe."

- A NOVARTIS HELLAS sales manager stated (as translated): "[T]he main issue is . . . that the doctors believe that the study was conducted in order to get paid for what they write, right?"

- A NOVARTIS HELLAS medical manager stated (as translated) that a clinical study "is a part of the marketing mix; we do not disagree that this is a type of benefit provided to the doctors. They know that they will get paid, this is what happens in reality."

- A NOVARTIS HELLAS brand manager stated that (as translated): "To be honest, the studies were conducted in a similar way in the past as well; they were conducted as marketing projects. That's within quotation marks. Between us."

40. NOVARTIS HELLAS, through its employees and agents, falsely recorded these payments related to EXACTLY as advertising and promotion expenses in NOVARTIS HELLAS's internal accounting records. By doing so, NOVARTIS HELLAS concealed their true and improper nature. These false records were consolidated into Novartis AG's financial records and were used to support Novartis AG's financial reporting to the SEC. As such, NOVARTIS HELLAS, through its employees and agents, knowingly and willfully conspired and agreed with others to cause the payments related to EXACTLY to be falsely recorded as legitimate expenses in Novartis AG's books, records, and accounts.

COUNT ONE
(Conspiracy to Violate the Antibribery Provisions of the FCPA)

41. Paragraphs 1 through 8 and 10 through 28 of this Information are realleged here.

42. Between in or about 2012 and in or about 2015, within the United States and elsewhere, defendant

NOVARTIS HELLAS S.A.C.I.

together with Novartis Hellas Employee 1, Novartis Hellas Employee 2, and others known and unknown, knowingly and willfully did combine, conspire, confederate, and agree together and with each other to commit an offense against the United States, that is: while in the territory of the United States, through its employees and agents, did corruptly commit acts in furtherance of an offer, payment, promise to pay, and authorization of the giving of anything of value to a foreign official and to any person, while knowing that all or a portion of such money and thing of value would be and had been offered, given, and promised to a foreign official for purposes of: (i) influencing acts and decisions of such foreign official in his or her official capacity; (ii) inducing such foreign official to do and omit to do acts in violation of the lawful duty of such official; (iii) securing any improper advantage; and (iv) inducing such foreign official to use his or her influence with a foreign government and agencies and instrumentalities thereof to affect and influence acts and decisions of such government and agencies and instrumentalities, in order to assist NOVARTIS HELLAS in obtaining and

retaining business for and with, and directing business to, NOVARTIS HELLAS, contrary to 15 U.S.C. § 78dd-3.

Object of the Conspiracy

43. The object of the conspiracy was for NOVARTIS HELLAS and its co-conspirators to gain improper business advantages for NOVARTIS HELLAS, including increased sales of Lucentis, a Novartis-branded drug, by bribing Greek State HCPs through sponsorships to attend international medical congresses.

Manner and Means of the Conspiracy

44. The manner and means by which NOVARTIS HELLAS and its co-conspirators and others sought to accomplish the object of the conspiracy included, among other things, the following:

a. NOVARTIS HELLAS, through certain of its employees and agents, including Novartis Hellas Employee 1 and Novartis Hellas Employee 2, sponsored Greek State HCPs to attend international congresses as a means to bribe and corruptly influence the HCPs to increase prescriptions of Lucentis.

b. NOVARTIS HELLAS paid for public and private ophthalmologists in Greece to attend international "medical congresses." These congresses were organized by various medical associations in the United States and Europe, and typically took place over several days in a destination city in the United States or Europe.

c. By sponsoring Greek State HCPs to attend congresses, NOVARTIS HELLAS paid for the costs associated with that Greek State HCP's attendance such as airfare, hotel accommodations, and congress registration fees. NOVARTIS HELLAS typically paid for travel costs associated with congresses through third-party travel agencies. For each individual Greek State HCP, the total cost to NOVARTIS HELLAS for attendance of an international congress often exceeded $6,000.

d. NOVARTIS HELLAS's policies stated that the purpose for sending HCPs to congresses was to provide scientific or educational information. In reality, however, sales employees at NOVARTIS HELLAS, including Novartis Hellas Employee 1, sometimes used international congresses to improperly influence and induce Greek State HCPs to increase prescriptions for Lucentis.

e. As part of the scheme, NOVARTIS HELLAS maintained internal documentation noting that HCPs with the highest potential and highest propensity to prescribe Lucentis would receive "investments," such as sponsorships to attend international congresses, while HCPs with lower potential and less propensity to prescribe Lucentis would receive no such "investments."

f. NOVARTIS HELLAS, through its employees and agents, falsely recorded the corrupt payments associated with congress sponsorships as legitimate advertising and promotion expenses in NOVARTIS HELLAS's internal accounting records. By recording these payments as

advertising and promotion expenses, NOVARTIS HELLAS concealed their true and corrupt nature.

Overt Acts

45. In furtherance of the conspiracy and to effect its object, NOVARTIS HELLAS and its co-conspirators committed or caused the commission of the following acts in the United States and elsewhere:

a. On or about September 27, 2012, NOVARTIS HELLAS's Lucentis Brand Team held a meeting to discuss the sales strategy for Greek State HCPs. Novartis Hellas Employee 1 and Novartis Hellas Employee 2 participated in the meeting at which it was discussed that Greek State HCPs "must understand that their participation in [specific congresses in the United States and Europe] will be cancelled if sales performance is not improved significantly."

b. In or about January 2013, Novartis Hellas Employee 1 prepared a presentation entitled "Action Plan KOLs" which detailed the various means through which Novartis Hellas Employee 1 and others at NOVARTIS HELLAS intended to target various Key Opinion Leaders in ophthalmology. One such Action Plan targeted Greek HCP 1, who worked at the Greek State-Owned Clinic. The Action Plan set forth how Novartis Hellas Employee 1 and others at NOVARTIS HELLAS intended to use certain "actions"—including sponsorship to U.S. congresses—to induce Greek HCP 1 to prescribe Lucentis. The Action Plan further stated that Novartis Hellas Employee 1 and others at NOVARTIS

HELLAS should convey the following message to Greek HCP 1: "to get you must write. No presents anymore."

c. In or about late 2013, employees of NOVARTIS HELLAS traveled to the United States and, while located in the United States, facilitated the attendance of Greek HCP 1 and others at the U.S. Academy's congress in New Orleans, Louisiana.

In violation of Title 18, United States Code, Section 371.

COUNT TWO
(Conspiracy to Violate the Books and Records Provision of the FCPA)

46. Paragraphs 1 through 8 and 10 through 40 of this Information are realleged here.

47. Between in or about 2009 and in or about 2010 and between in or about 2012 and in or about 2015 within the United States and elsewhere, defendant

NOVARTIS HELLAS S.A.C.I.

together with others known and unknown, knowingly and willfully did combine, conspire, confederate, and agree together and with each other to commit an offense against the United States, that is: to knowingly and willfully falsify and cause to be falsified books, records, and accounts required, in reasonable detail, to accurately and fairly reflect the transactions and dispositions of the assets of Novartis AG, an issuer within the meaning of the FCPA, contrary to 15 U.S.C. §§ 78m(b)(2)(A), 78m(b)(5), and 78ff(a).

Object of the Conspiracy

48. The object of the conspiracy was for NOVARTIS HELLAS and its co-conspirators to cause certain payments to be falsely recorded in Novartis AG's books, records, and accounts as a method to conceal the corrupt payments to Greek State HCPs in furtherance of NOVARTIS HELLAS's effort to obtain and retain business relating to Lucentis, and to conceal the improper payments to HCPs in connection with an epidemiological study intended to increase sales of certain Novartis-branded prescription drugs.

Manner and Means of the Conspiracy

49. The manner and means by which NOVARTIS HELLAS and its co-conspirators sought to accomplish the object of the conspiracy included, among other things, the following:

a. NOVARTIS HELLAS, through its employees and agents, falsely recorded the corrupt payments associated with congress sponsorships as legitimate advertising and promotion expenses in NOVARTIS HELLAS's internal accounting records. The false books and records failed to accurately reflect the true nature of the transactions and disposition of Novartis AG's assets.

b. NOVARTIS HELLAS, through its employees and agents, falsely recorded improper payments related to EXACTLY as advertising and promotion expenses in NOVARTIS HELLAS's internal accounting records.

The false books and records failed to accurately reflect the true nature of the transactions and disposition of Novartis AG's assets.

Overt Acts

50. In furtherance of the conspiracy and to effect its object, NOVARTIS HELLAS and its co-conspirators committed or caused the commission of the following acts in the United States and elsewhere:

a. On or about September 27, 2012, NOVARTIS HELLAS's Lucentis Brand Team held a meeting to discuss the sales strategy for Greek State HCPs. Novartis Hellas Employee 1 and Novartis Hellas Employee 2 participated in the meeting at which it was discussed that Greek State HCPs "must understand that their participation in [specific congresses in the United States and Europe] will be cancelled if sales performance is not improved significantly."

b. In or about January 2013, Novartis Hellas Employee 1 prepared a presentation entitled "Action Plan KOLs" which detailed the various means through which Novartis Hellas Employee 1 and others at NOVARTIS HELLAS intended to target various Key Opinion Leaders in ophthalmology. One such Action Plan targeted Greek HCP 1, who worked at the Greek State-Owned Clinic. The Action Plan set forth how Novartis Hellas Employee 1 and others at NOVARTIS HELLAS intended to use certain "actions"—including sponsorship to U.S. congresses—to induce Greek HCP 1 to prescribe Lucentis. The Action Plan further stated that Novartis Hellas Employee 1 and others at NOVARTIS

HELLAS should convey the following message to Greek HCP 1: "to get you must write. No presents anymore."

c. In or about late 2013, employees of NOVARTIS HELLAS traveled to the United States and, while located in the United States, facilitated the attendance of Greek HCP 1 and others at the U.S. Academy's congress in New Orleans, Louisiana.

d. NOVARTIS HELLAS, through its employees and agents, falsely recorded the payments associated with Greek HCP 1's attendance at the U.S. Academy's congress as advertising and promotion expenses. By doing so, NOVARTIS HELLAS concealed their true and corrupt nature. These false records were consolidated into Novartis AG's financial records and used to support Novartis AG's financial reporting to the SEC.

e. From in or about April 2009 through in or about December 2009, NOVARTIS HELLAS and HCPs conducted the EXACTLY study which was designed to target over 2,200 HCPs and over 44,000 patients. Ultimately, NOVARTIS HELLAS, through its employees and agents, made improper payments to HCPs related to EXACTLY, which was intended to increase sales of certain Novartis-branded prescription drugs.

f. NOVARTIS HELLAS, through its employees and agents, falsely recorded these payments related to EXACTLY as advertising and promotion expenses in NOVARTIS HELLAS's internal accounting records. By doing so, NOVARTIS HELLAS, concealed their true and improper nature. These

false records were consolidated into Novartis AG's financial records and were used to support Novartis AG's financial reporting to the SEC.

In violation of Title 18, United States Code, Section 371.

6/22/2020

ROBERT ZINK
Chief, Fraud Section
Criminal Division
U.S. Department of Justice

CRAIG CARPENITO
United States Attorney
District of New Jersey

CASE NUMBER: 20-cr-538

United States District Court
District of New Jersey

UNITED STATES OF AMERICA

v.

NOVARTIS HELLAS S.A.C.I.

INFORMATION

18 U.S.C. § 371

CRAIG CARPENITO
UNITED STATES ATTORNEY
NEWARK, NEW JERSEY

BERNARD J. COONEY
SENIOR TRIAL COUNSEL
JOSHUA L. HABER
ASSISTANT U.S. ATTORNEY
(973) 645-2823