# SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General ("OIG-HHS") of the Department of Health and Human Services ("HHS") (collectively, the "United States"), and Novartis Pharmaceuticals Corporation (hereafter collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

A. Novartis Pharmaceuticals Corporation ("Novartis") is a Delaware corporation with principal executive offices located in East Hanover, New Jersey. Novartis markets pharmaceutical products, including Gilenya and Afinitor. In 2010, the United States Food and Drug Administration ("FDA") approved Gilenya for the treatment of patients with relapsing forms of multiple sclerosis ("MS"). In 2009, the FDA approved Afinitor as a treatment for advanced renal cell carcinoma ("RCC") for use after failure of treatment with either of two other RCC drugs; in May 2011, the FDA approved Afinitor to treat progressive neuroendocrine tumors of pancreatic origin ("PNET").

B. The United States contends that Novartis caused to be submitted claims for payment for Afinitor to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll ("Medicare").

C. When a patient obtains a prescription drug covered by Medicare Part D, the patient may be required to make a payment, which may take the form of a "copayment," "coinsurance," or "deductible" (collectively "copays"). The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, prohibits pharmaceutical companies from paying remuneration to induce Medicare beneficiaries to purchase, or their physicians to prescribe, drugs that are reimbursed by Medicare.

D. The Assistance Fund ("TAF"), National Organization for Rare Disorders ("NORD"), and Chronic Disease Fund ("CDF") are each entities claiming 501(c)(3) status for tax purposes that operated funds that paid the copays of certain patients, including Medicare patients.

E. The United States contends that it has certain civil claims, as specified in Paragraph 2 below, against Novartis for engaging in the conduct below (hereinafter referred to as the "Covered Conduct"). Specifically, the United States alleges:

At certain intervals during the period from January 1, 2010, through December 31, 2014, Novartis used TAF as a conduit to pay kickbacks to Medicare patients taking Gilenya and used NORD and CDF as conduits to pay kickbacks to Medicare patients taking Afinitor.

With respect to TAF, in October 2012, Novartis learned from Express Scripts, which then was managing Novartis's free drug program for Gilenya, that Novartis was providing free Gilenya to 364 patients who would become eligible for Medicare the following year. Novartis and Express Scripts transitioned these patients to Medicare Part D so that, in the future, Novartis would obtain revenue from Medicare when the patients filled their prescriptions for Gilenya. Knowing that these patients could not afford co-pays for Gilenya, Novartis developed a plan for Novartis to cover their co-pays through TAF, which operated a fund that, ostensibly, offered co-pay assistance to any MS patient who met TAF's financial eligibility criteria, regardless of which MS drug the patient was taking. Specifically, at the same time it made a payment to TAF, Novartis arranged for TAF to open its MS fund at 6:00 p.m. on Friday, December 14, 2012, and for Express Scripts to have personnel working overtime that night and the following morning submitting applications to TAF on behalf of patients who previously had been receiving free Gilenya from Novartis. Novartis knew that the timing of the opening of the fund and the

readiness of Express Scripts to submit applications on behalf of Gilenya patients at that time would result in Gilenya patients receiving a disproportionate share of the grants from the fund while it was open. After the fund closed on Saturday, December 15, 2012, Novartis confirmed that, during the brief period the fund had been open, TAF used Novartis's money to provide 374 Gilenya patients with grants for Medicare co-pay assistance in 2013. Novartis subsequently made further payments to TAF, and TAF provided many of these same Gilenya patients with grants for Medicare co-pay assistance in 2014.

With respect to NORD, Novartis learned that, as of the 2010 donation year, no other manufacturer of RCC medications would be contributing to a pre-existing NORD RCC copay assistance fund. Novartis knew that Afinitor was approved for use as a second-line RCC treatment only, and only when certain first-line products had failed. Novartis also knew, therefore, that any copay assistance given to patients for initial RCC treatments would not be used to provide co-pay assistance to patients on Afinitor. Novartis informed NORD that it would be willing to donate to its RCC fund if NORD narrowed the fund's eligibility definition so as not to cover first line treatments. Novartis wanted the definition narrowed to ensure that a greater amount of its donations would subsidize its product, as opposed to others. NORD then created a new fund entitled "Advanced Renal Cell Carcinoma Second Line Co-Payment Assistance Program." This fund excluded any patients seeking assistance with first-line RCC treatments and disproportionally funded patients taking Afinitor compared to its overall usage rate among all RCC drugs. Novartis financed this NORD fund through 2014.

With respect to CDF, in 2012, after Afinitor was approved to treat PNET, Novartis asked CDF to open a copay assistance fund to pay Afinitor copays for PNET patients. At that time, Novartis knew that the FDA had approved a competing drug to treat PNET. Nonetheless, with

Novartis's knowledge, CDF launched a fund labeled "PNET" that paid the copays of Afinitor patients only and not those of patients seeking assistance for the other PNET drug. Novartis continued with this understanding as the sole donor to this supposed "PNET" fund through 2014.

As a result of the foregoing conduct, the United States contends that Novartis caused false claims to be submitted to Medicare.

F. In consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Novartis shall pay to the United States fifty-one million, two hundred fifty thousand dollars ($51,250,000), plus interest at a rate of 3.00% from July 31, 2019, through the day before full payment (the "Settlement Amount"), no later than ten days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the Office of the United States Attorney for District of Massachusetts. Of the Settlement Amount, $25,625,000 is restitution to the United States.

2. Subject to the exceptions in Paragraph 4 (concerning excluded claims) below, and conditioned upon Novartis' full payment of the Settlement Amount, the United States releases Novartis, together with its predecessors, and its current and former divisions, parents, subsidiaries, successors and assigns, from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-33, the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-12, or the common law theories of payment by mistake, unjust enrichment, and fraud.

3. In consideration of the obligations of Novartis in this Agreement and the Corporate Integrity Agreement ("CIA") entered into between OIG-HHS and Novartis, and conditioned upon Novartis' full payment of the Settlement Amount, the OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Novartis under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in this Paragraph and in Paragraph 4 (concerning excluded claims), below. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Novartis from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 4, below.

4. Notwithstanding the releases given in paragraphs 2 and 3 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any criminal liability;

c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. Any liability based upon obligations created by this Agreement;

f. Any liability of individuals;

g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;

h. Any liability for failure to deliver goods or services due; and

i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

5. Novartis waives and shall not assert any defenses Novartis may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

6. Novartis fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including for attorney's fees, costs, and expenses of every kind and however denominated) that Novartis has asserted, could have asserted, or may assert in the future against the United States, and its agencies, officers, agents, employees, and servants related to the Covered Conduct and the United States' investigation and prosecution thereof.

7. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (*e.g.*, Medicare Administrative Contractor, fiscal intermediary, carrier) or any state payer, related to the Covered

Conduct; and Novartis agrees not to resubmit to any Medicare contractor or any state payer any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

8. Novartis agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Novartis, its present or former officers, directors, employees, shareholders, and agents in connection with:

(1) the matters covered by this Agreement;

(2) the United States' audit(s), and any civil or criminal investigations of the matters covered by this Agreement;

(3) Novartis' investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and any civil or criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);

(4) the negotiation and performance of this Agreement;

(5) the payment Novartis makes to the United States pursuant to this Agreement; and

(6) the negotiation of, and obligations undertaken pursuant to the CIA to: (i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (ii) prepare and submit reports to the OIG-HHS,

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program ("FEHBP") (hereinafter referred to as "Unallowable Costs"). However, nothing in paragraph 8.a.(6) that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to Novartis.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Novartis, and Novartis shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Novartis or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Novartis further agrees that, within 90 days of the Effective Date of this Agreement, it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Novartis or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Novartis agrees that the United States, at a minimum, shall be entitled to recoup from Novartis any overpayment plus applicable interest and penalties as a result of the

inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Novartis or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Novartis or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Novartis' books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

9. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 10 (waiver for beneficiaries paragraph), below.

10. Novartis agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

11. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

12. Each Party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

13. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of Massachusetts. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

14. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

15. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

16. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

17. This Agreement is binding on Novartis' successors, transferees, heirs, and assigns.

18. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

19. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

**THE UNITED STATES OF AMERICA**

**DATED:** **BY:** GREGG SHAPIRO Digitally signed by GREGG SHAPIRO Date: 2020.06.30 17:07:29 -04'00'

**GREGG SHAPIRO**
**ABRAHAM GEORGE**
Assistant United States Attorneys
United States Attorney's Office
District of Massachusetts

**DATED:** 6/30/2020 **BY:**

**SARAH ARNI**
**AUGUSTINE RIPA**
Attorneys
Commercial Litigation Branch
Civil Division
United States Department of Justice

**DATED:** **BY:** GREGORY DEMSKE Digitally signed by GREGORY DEMSKE Date: 2020.06.30 15:57:57 -04'00'

**LISA M. RE**
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

**NOVARTIS PHARMACEUTICALS CORPORATION**

**DATED:** 6/29/2020 **BY:** _____

**ELIZABETH MCGEE**
General Counsel, US Pharma
US Country Head Legal
Novartis Pharmaceuticals Corporation

**DATED:** **BY:** _____

**ROSS GALIN**
O'Melveny & Myers LLP
Counsel for Novartis Pharmaceuticals Corporation

**NOVARTIS PHARMACEUTICALS CORPORATION**

**DATED:** **BY:** _____

**ELIZABETH MCGEE**
General Counsel, US Pharma
US Country Head Legal
Novartis Pharmaceuticals Corporation

**DATED:** 6/30/20 **BY:** _____

**ROSS GALIN**
O'Melveny & Myers LLP
Counsel for Novartis Pharmaceuticals Corporation