

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 Astellas Pharma US, Inc. (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. Astellas Pharma US, Inc. (“Astellas”) is a Delaware corporation with principal executive offices located in Northbrook, Illinois. Astellas manufactures and markets pharmaceutical products, including Xtandi. During the relevant time period, Xtandi was indicated for metastatic-castration-resistant prostate cancer (“mCRPC”).

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

C. When a Medicare 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. Patient Access Network Foundation (“PANF”), an entity claiming 501(c)(3) status for tax purposes, operated funds that paid the copays of certain patients, including Medicare patients. Chronic Disease Fund (“CDF”), an entity claiming 501(c)(3) status for tax purposes, 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 Astellas for engaging in the conduct below (hereinafter referred to as the “Covered Conduct”). Specifically, the United States has alleged and does allege:

During the period July 1, 2013, through December 31, 2014, Astellas used PANF and CDF as conduits to pay the copay obligations of Medicare patients taking Xtandi.

After the launch of Xtandi in September 2012, Astellas donated to mCRPC funds at CDF and PANF. Xtandi is an androgen receptor inhibitor (“ARI”); none of the other major drugs to treat mCRPC, including Xtandi’s main competitor, is an ARI. On or about May 17, 2013, Astellas contacted PANF and CDF to ask about the creation of ARI funds, which would cover mCRPC patients’ copays for ARIs, but not for other mCRPC drugs. On July 1, 2013, both PANF and CDF opened ARI funds. Astellas was the only donor to both funds. Because the funds covered only ARIs, and because the other ARIs on each fund’s formulary were either generic or had very low market share, Astellas knew that Xtandi would likely account for the vast majority of utilization from each fund. In fact, Xtandi patients received nearly all of the assistance from the ARI funds at PANF and CDF. Astellas donated to the ARI funds between July 1, 2013 and December 2013. Astellas stopped donating to CDF at the end of 2013. PANF’s ARI fund remained open until February 17, 2014, but PANF continued to pay the copays for patients in the ARI fund from funds allocated to the ARI fund for the remainder of 2014, even after the ARI fund had closed. During the time that the ARI funds were open, Astellas promoted the existence of the ARI funds as an advantage for Xtandi over competing mCRPC drugs in an effort to persuade medical providers to prescribe Xtandi.

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

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

TERMS AND CONDITIONS

1. Astellas shall pay to the United States one hundred million dollars (\$100,000,000), plus interest at a rate of 2.875% from June 28, 2018, 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 the District of Massachusetts. Of the Settlement Amount, \$50,000,000 is restitution to the United States.

2. Subject to the exceptions in Paragraph 4 (concerning excluded claims) below, and conditioned upon Astellas’ full payment of the Settlement Amount, the United States releases Astellas, together with its current and former direct and indirect parent corporations and limited liability companies (“parents”); its and their affiliates, direct and indirect subsidiaries, brother and sister corporations and divisions; and its and their respective current and former corporate owners; and the predecessors, successors, transferees, and assigns of any of them, 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 Astellas in this Agreement and the Corporate Integrity Agreement (“CIA”) entered into between OIG-HHS and Astellas, and conditioned upon Astellas’ 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 Astellas 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 Astellas 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. Astellas waives and shall not assert any defenses Astellas 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. Astellas 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 Astellas 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 Astellas 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. Astellas 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 Astellas, 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) Astellas' 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 Astellas 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 Astellas.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Astellas, and Astellas 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 Astellas or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Astellas 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 Astellas 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. Astellas agrees that the United States, at a minimum, shall be entitled to recoup from Astellas 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 Astellas or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Astellas 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 Astellas' 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. Astellas 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 Astellas' 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: 4/25/19

BY:


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

DATED: 4/25/19

BY:


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

DATED:

BY:

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

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

DATED:

BY:

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

DATED: 04/24/2019

BY:

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

ASTELLAS PHARMA US, INC.

DATED:

4/18/19

BY:

CATHERINE B. LEVITT
Secretary
Astellas Pharma US, Inc.

DATED:

4/19/19

BY:

THOMAS M. GALLAGHER
Pepper Hamilton LLP
Counsel for Astellas Pharma US, Inc.