

SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is entered into between Astellas Pharma U.S., Inc. (“Astellas”) and Ronald J. Streck (“Relator”) (collectively “the Parties”), through their authorized representatives.

RECITALS

A. Astellas is a Delaware corporation, headquartered at One Astellas Way, Deerfield, Illinois 60062.

B. On November 24, 2014, Ronald J. Streck filed a *qui tam* action in the United States District Court for the Northern District of Illinois captioned *United States, State of California, State of Colorado, State of Connecticut, State of Delaware, State of Florida, State of Georgia, State of Hawaii, State of Illinois, State of Indiana, State of Iowa, State of Louisiana, State of Maryland, The Commonwealth of Massachusetts, State of Michigan, State of Minnesota, State of Montana, State of Nevada, State of New Jersey, State of New Mexico, State of New York, State of North Carolina, State of Oklahoma, State of Rhode Island, State of Tennessee, State of Texas, The Commonwealth of Virginia, State of Washington, State of Wisconsin, The District of Columbia, ex rel. Ronald J. Streck v. Takeda Pharmaceuticals America, Inc., et al.*, 1:14-cv-09412, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) and the false claims statutes of the plaintiff states (the “Civil Action”). Relator filed an amended complaint on or about September 7, 2018. ECF No. 77. Astellas was named as a defendant in Relator’s original and amended complaint.

C. The States and the District of Columbia who are named as plaintiffs in the Civil Action are referred to herein as “Plaintiff States.” By Order dated January 26, 2018, all claims asserted by Relator in the Civil Action on behalf of Maryland were

dismissed without prejudice. This Agreement covers *qui tam* claims asserted by Relator in the Civil Action on behalf of the United States, and on behalf of the other twenty-eight Plaintiff States (the Plaintiff States, except for Maryland). Those twenty-eight states are referred to herein as “Medicaid Participating States.”

D. At all relevant times, Astellas participated in the Medicaid Drug Rebate Program, 42 U.S.C. § 1396r-8, which is part of the federal Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396w-5.

E. In the Civil Action, Relator contends that Astellas has violated the False Claims Act, 31 U.S.C. §§ 3729, *et seq.*, and the false claims statutes of the Medicaid Participating States, by engaging in the following alleged conduct during the period from October 1, 2007 through March 31, 2016 (hereafter referred to as the “Covered Conduct”):

1. Pursuant to the Medicaid Drug Rebate Program, Astellas was required to report the Average Manufacturer Price (“AMP”) for each of its covered outpatient drugs to the Centers for Medicare and Medicaid Services (“CMS”) on a monthly and quarterly basis, and to pay quarterly rebates to state Medicaid programs that were based, in part, on the quarterly AMPs reported by Astellas. Prior to enactment of the Affordable Care Act (“ACA”), the AMP for a drug generally was based on the average unit price paid to the manufacturer for the drug by wholesalers for drugs distributed to the retail pharmacy class of trade, including cash discounts and other price concessions that reduced the actual price paid for the drug. The ACA revised the definition of AMP, in part, by replacing the term “retail pharmacy class of trade” with “retail community pharmacies” and including manufacturer direct sales to pharmacies. Both before and after

enactment of the ACA, bona fide service fees are excluded from manufacturers' AMP calculations.

2. Astellas entered into services agreements with wholesalers ("Services Agreements") to facilitate the distribution and sale of the pharmaceuticals listed on Attachment A hereto ("the Covered Drugs"). Pursuant to the Services Agreements, the wholesalers performed various specified services, and Astellas compensated the wholesalers for performing those services.

3. Relator contends that, for quarterly rebate periods from October 1, 2007 through March 31, 2016, Astellas improperly treated compensation provided to the wholesalers pursuant to the Services Agreements as price reductions, rather than as bona fide service fees, when calculating and reporting quarterly AMPs to CMS for the Covered Drugs. As a result of Astellas's reporting such improperly reduced AMPs, Relator contends that Astellas underpaid quarterly rebates owed to the states for the Covered Drugs under the Medicaid Drug Rebate Program, and caused the United States to be overcharged for its payments to the states for the Medicaid Program.

4. Covered Conduct does not include the following time periods with respect to the following states:

- Connecticut: conduct before October 5, 2009
- Iowa: conduct before July 1, 2010
- Minnesota: conduct before July 1, 2010
- Montana: conduct before July 1, 2009
- Washington: conduct before June 7, 2012
- Wisconsin: conduct after July 14, 2015

F. Astellas denies Relator's allegations. This Settlement Agreement is neither an admission of facts nor liability by Astellas, nor is it a concession by Relator that his claims are not well founded.

G. Relator claims entitlement under 31 U.S.C. § 3730(d)(2) and under the corresponding provisions of the false claims statutes of the Plaintiff States, to a share of the proceeds of this Settlement Agreement and to Relator's reasonable expenses, attorneys' fees and costs.

THEREFORE, to avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and 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 and the Medicaid Participating States, collectively, the sum of \$18,000,000.00 ("Settlement Amount"), of which nine million dollars (\$9,000,000) is restitution, as follows:

a. Astellas shall pay to the United States the sum of \$10,340,065.42 (the "Federal Settlement Amount"). Astellas shall pay the Federal Settlement Amount to the United States by electronic funds transfer pursuant to written instructions to be provided by the United States, and shall make that payment within ten (10) days of the later of the Effective Date of this Agreement or written confirmation that the United States consents to the dismissal referenced in paragraph 3.

b. Astellas shall pay to the Medicaid Participating States the sum of \$ 7,659,934.58 (the "State Settlement Amount"), as reflected by state in Attachment B. Astellas shall pay the State Settlement Amount by electronic funds transfer pursuant to written instructions

to be provided by representatives for the Medicaid Participating States, and shall make that payment within ten (10) days of the later of the Effective Date of this Agreement, or written confirmation that all of the Medicaid Participating States consent to the dismissal referenced in paragraph 3.

2. Pursuant to 31 U.S.C. § 3730(d)(2) and its state law analogues, Astellas shall pay the sum of \$950,000 for attorney's fees, costs and expenses ("Relator's Expenses") to Relator's counsel within ten (10) days of the Effective Date of this Agreement, pursuant to written instructions to be provided by Relator's counsel.

3. Upon payment by Astellas of the Federal Settlement Amount, the State Settlement Amount, and Relator's Expenses in accordance with Paragraphs 1 and 2, Relator and Astellas shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal, pursuant to Rule 41(a)(1), dismissing with prejudice (as to Relator, the United States, and the Medicaid Participating States) all claims asserted by Relator against Astellas in the Civil Action for the Covered Conduct, including any claim for attorneys fees and expenses under 31 U.S.C. § 3732(d)(2) and dismissing any claims asserted by Relator against Astellas in the Civil Action for other than the Covered Conduct with prejudice to Relator but without prejudice to the United States or the Plaintiff States. The Joint Stipulation of Dismissal shall provide that dismissal is subject to the consent of the United States and the Medicaid Participating States pursuant to the False Claims Act and corresponding state false claims statutes, and the Parties will coordinate the filing of the Joint Stipulation of Dismissal with the filing by the federal and state governments of applicable notices of consent. The Joint Stipulation of Dismissal shall expressly provide that the Court retain jurisdiction of the Civil Action for purposes of enforcing this Settlement Agreement, and to address any unresolved claims by Relator against the United States or any of the Medicaid

Participating States for a share of the proceeds of this Settlement Agreement pursuant to 31 U.S.C. § 3730(d)(2) and the corresponding provisions of the false claims statutes of the Medicaid Participating States.

4. This Agreement is contingent upon: (a) the dismissal of the federal claims asserted by Relator against Astellas in this Civil Action, with prejudice to the United States as to such federal claims for the Covered Conduct and without prejudice to the United States as to any such federal claims for other than the Covered Conduct; and (b) the dismissal of the state claims asserted by Relator against Astellas in this Civil Action with prejudice to the Medicaid Participating States as to such state claims for the Covered Conduct and without prejudice to the Medicaid Participating States as to any such state claims for other than the Covered Conduct.

5. Upon Astellas's payment of the Settlement Amount and the Relator's Expenses, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, releases Astellas fully and completely and without limitation, including each of its past and present parents, subsidiaries, divisions, affiliates (defined as an entity that is wholly owned or controlled by Astellas), officers, directors, employees, agents, attorneys, predecessors and successors (successor is defined as an entity that exercises complete control or ownership over Astellas) from any and all claims or actions under any federal, state or local statute or regulation, or any common law claim. However, a successor will only be released from claims that Relator asserted or could have asserted against Astellas at the time the Amended Complaint was filed. Relator reserves all claims against any successor that are not expressly released in this Agreement, including all claims asserted against Astellas's co-defendants in this Civil Action irrespective of whether they later become a successor to Astellas. Further, Relator's release in this Paragraph shall not operate as a release of any claims, of any kind, that the United States and/or the Plaintiff States may have

against any individual or entity, whether arising from or related to the allegations asserted against Astellas in the Civil Action or otherwise.

6. Astellas fully and finally releases Relator, his heirs, successors, attorneys, agents, and assigns from any claims (including for attorney's fees, costs, and expenses of every kind and however denominated) that Astellas has asserted or could have asserted against Relator, his heirs, successors, attorneys, agents from any and all claims of any kind, including any under any federal, state or local statute or regulation, or any common law claim.

7. Nothing in this Agreement, or the Parties' willingness to enter into this Agreement, shall be construed as an admission of facts or liability by any person. This Agreement shall not be admissible in evidence in any federal, state, administrative, investigative or arbitration proceeding except for the purposes of enforcement of its terms, or to establish a defense to any action, suit or other proceeding that may be instituted or attempted based on or related to the claims in this Civil Action.

8. Except as otherwise provided in this Agreement, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

9. Each party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

10. 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 Northern District of Illinois. 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.

11. This Agreement constitutes the complete agreement between the Parties and shall be construed and interpreted to effectuate the Parties' intent. This Agreement may not be amended except by written consent of the Parties.

12. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below. Each Party agrees to perform any further acts and to execute any further documents reasonably necessary to carry out the terms of this Agreement.

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

14. This Agreement is binding on Astellas's successors, transferees, heirs, and assigns.


15. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

16. This Agreement is effective on the date of signature of the last signatory to the Agreement ("Effective Date"). Facsimiles of signatures and/or electronic signatures in portable document format (.pdf) shall constitute acceptable, binding signatures for purposes of this Agreement.

[Signature page follows]

RONALD J. STRECK – RELATOR

DATED: 9/2/21

BY: 
RONALD J. STRECK
Relator

DATED: 9/2/21

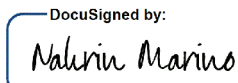
BY: *Dan Miller*
DANIEL R. MILLER
Walden, Macht & Haran, LLP

DATED: 9/2/21

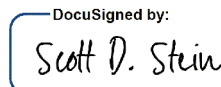
BY: 
ROBERT JACKSON MARTIN, IV
Martin Law, P.C.

ASTELLAS PHARMA, U.S., INC.

DATED: 13 September 2021

BY: 
B65D834F816A4F3...
NAHRIN MARINO
Senior Vice President, Legal Head of
Commercial, Regulatory, Medical &
Development

DATED: 13 September 2021

BY: 
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SCOTT D. STEIN
Counsel for Astellas Pharma, U.S., Inc.