

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

RECITALS

A. Actelion Pharmaceuticals US, Inc. (“Actelion”), is a Delaware corporation with principal executive offices located in South San Francisco, California. Actelion manufactures and markets pharmaceutical products, including Tracleer, Ventavis, Veletri, and Opsumit (collectively the “Subject Drugs”), that are approved to treat pulmonary arterial hypertension (“PAH”).

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

C. When a Medicare beneficiary obtains a prescription drug covered by Medicare Part B or Part D, the beneficiary 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. Caring Voice Coalition (“CVC”), an entity claiming 501(c)(3) status for tax purposes, operated a fund that paid the copays of certain PAH patients, including Medicare

patients. During the time period from January 1, 2014, through December 31, 2015, CVC operated a PAH fund that paid the copays of certain patients, including Medicare patients, prescribed the Subject Drugs and certain non-Actelion drugs also indicated to treat PAH.

E. The United States contends that it has certain civil claims, as specified in Paragraph 2 below, against Actelion for engaging in the conduct below during the period from January 1, 2014, through December 31, 2015 (hereinafter referred to as the “Covered Conduct”). Specifically, the United States alleges:

Actelion made donations to CVC’s PAH fund and used it as a conduit to pay the copay obligations of thousands of Medicare patients taking the Subject Drugs and to induce those patients’ purchases of the Subject Drugs, because it knew that the prices Actelion set for the Subject Drugs otherwise could pose a barrier to those purchases. From January 1, 2014, through August 2015, Actelion routinely obtained data from CVC detailing how many patients on each Subject Drug CVC had assisted, how much CVC had spent on those patients, and how much CVC expected to spend on those patients in the future. Actelion received this information through funding requests, telephone calls, and written reports. Actelion used this information to budget for future payments to CVC on a drug-specific basis and to confirm that its contribution amounts to CVC were sufficient to cover the copays of patients taking the Subject Drugs, but not of patients taking other manufacturers’ PAH drugs. Actelion engaged in this practice even though CVC warned the company against receiving data concerning CVC’s expenditures on copays for the Subject Drugs.

During the time period of January 1, 2014, through December 31, 2015, Actelion had a policy of not permitting Medicare patients to participate in its free drug program, which was open to other financially needy patients, even if those Medicare patients could not afford their

copays for Actelion drugs. Instead, in order to generate revenue from Medicare and to induce purchases of the Subject Drugs, Actelion referred Medicare patients prescribed the Subject Drugs to CVC, which resulted in claims to federal healthcare programs to cover the cost of the drugs.

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

The Covered Conduct concluded prior to the acquisition of Actelion by Johnson & Johnson on June 16, 2017. Johnson & Johnson was not involved, directly or indirectly, in the Covered Conduct and the allegations above do not relate in any way to Johnson & Johnson.

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

TERMS AND CONDITIONS

1. Actelion shall pay to the United States three hundred sixty million dollars (\$360,000,000), plus interest at a rate of 2.875% from July 1, 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 District of Massachusetts. Of the Settlement Amount, \$180,000,000 constitutes restitution to the United States.

2. Subject to the exceptions in Paragraph 4 (concerning excluded claims) below, and conditioned upon Actelion’s full payment of the Settlement Amount, the United States releases Actelion, together with its predecessors, and its current and former direct and indirect parent corporations and each of their current and former direct and indirect subsidiaries, brother or sister corporations, divisions, and affiliates; 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; any statutory provision for which the Civil Division of the Department of Justice has actual and present authority to assert and compromise pursuant to 28 CFR Part 0, Subpart I, 0.45(d); or the common law theories of payment by mistake, unjust enrichment, disgorgement and fraud.

3. OIG-HHS expressly reserves all rights to institute, direct, or to maintain any administrative action seeking exclusion against Actelion and/or its officers, directors, and employees from Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) under 42 U.S.C. § 1320a-7(a) (mandatory exclusion), or 42 U.S.C. § 1320a-7(b) or 42 U.S.C. § 1320a-7a (permissive exclusion).

4. Notwithstanding the releases given in Paragraph 2 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. Actelion waives and shall not assert any defenses Actelion 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. Actelion 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 Actelion 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 Actelion 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. Actelion 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 Actelion, 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) Actelion's 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; and
- (5) the payment Actelion makes to the United States pursuant to this Agreement.

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").

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

c. Treatment of Unallowable Costs Previously Submitted for Payment:

Actelion 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 Actelion 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. Actelion agrees that the United States, at a minimum, shall be entitled to recoup from Actelion 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 Actelion or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Actelion 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 Actelion's 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 2, above, and Paragraph 10 (waiver for beneficiaries paragraph), below.

10. Actelion 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 Actelion's 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: 12/6/18

BY:

[REDACTED]

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

DATED: 12/4/18

BY:

[REDACTED]

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

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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

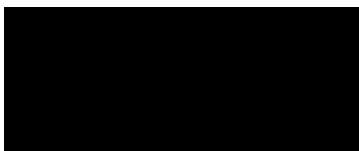
DATED: 12/04/2018 **BY:**

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

ACTELION PHARMACEUTICALS US, INC.

DATED: 12/5/2018

BY:



SERGE MESSERLIAN
OFFICER

Actelion Pharmaceuticals US, Inc.

DATED:

BY:

J. SEDWICK SOLLERS
MARK A. JENSEN
BRANDT LEIBE
DANIEL C. SALE

King & Spalding LLP
Counsel for Actelion Pharmaceuticals US, Inc.

ACTELION PHARMACEUTICALS US, INC.

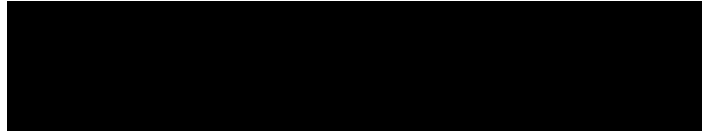
DATED:

BY:

[Name]

[Title]

Actelion Pharmaceuticals US, Inc.



DATED: 12/5/18

BY:

J. SEDWICK SOLLERS

MARK A. JENSEN

BRANDT LEIBE

DANIEL C. SALE

King & Spalding LLP

Counsel for Actelion Pharmaceuticals US, Inc.