

## STATE SETTLEMENT AGREEMENT

### I. PARTIES

This Settlement Agreement ("Agreement") is entered into between the State of California ("the State"), Genentech, Inc. ("Genentech") and OSI Pharmaceuticals, LLC ("OSI") (together referred to as the "Defendants") hereinafter collectively referred to as "the Parties," through their authorized representatives.

### II. PREAMBLE

A. Genentech is a Delaware corporation with its principal place of business in California. OSI Pharmaceuticals, Inc. was a Delaware corporation with its principal place of business in New York. In June 2010, OSI was acquired by Astellas US Holding, Inc., and, in March 2011, was converted to a Delaware limited liability company, OSI Pharmaceuticals, LLC. Defendants manufactured, distributed, marketed, and promoted an oncology drug sold under the trade name Tarceva. Tarceva is approved by the U.S. Food and Drug Administration ("FDA") for multiple indications, including for the treatment of patients with "locally advanced or metastatic non-small cell lung cancer after failure of at least one prior chemotherapy regimen."

B. On February 22, 2011, Relator filed a *quidam* action pursuant to the provisions of the False Claims Act, 31 U.S.C. § 3730(b), and various state false claims act statutes, in the United States District Court for the Northern District of California, Case Number CV 11-0822-MEJ, captioned *United States et al. ex rel. Brian Shields v. Genentech, Inc., et al.*, which was later amended on May 16, 2011, and again on September 29, 2011 (hereinafter "the Civil Action"). The Civil Action asserted state

claims on behalf of the following plaintiff states: California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Wisconsin, and the District of Columbia.

C. Defendants have entered into a separate civil settlement agreement (the "Federal Settlement Agreement") with the United States (as that term is defined in the Federal Settlement Agreement):

D. The State contends that Defendants caused claims for payment to be submitted to the Medicaid Program (Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396w(5)).

E. Tarceva treats non-small cell lung cancer ("NSCLC") by targeting the epidermal growth factor receptors ("EGFRs") in cancerous cells. In 2013, the FDA approved Tarceva to treat patients with certain EGFR mutations "first line" (i.e. before the failure of at least one prior chemotherapy regimen). One measure of health status of NSCLC patients may be expressed in terms of performance status ("PS") on the Eastern Cooperative Oncology Group ("ECOG") performance status scale, with the healthiest patients classified as ECOG PS 0 or 1.

F. The State contends that it has certain civil claims against Defendants arising from their distribution, marketing, and sale of Tarceva for NSCLC from 2006 through 2011:

Defendants made misleading representations to physicians and other health care providers about Tarceva's effectiveness to treat certain NSCLC patients when there was

little evidence to show that Tarceva was effective, unless the patients also had an EGFR mutation or unless they had never smoked. As a result, Defendants knowingly caused false or fraudulent claims for Tarceva to be submitted to the State's Medicaid Program for Tarceva to treat NSCLC, as a first line of therapy, in current or former smokers classified as ECOG PS 0 or I, who did not have a known EGFR mutation, when such first line use was not approved by the FDA, was not a medically accepted indication as defined by 42 U.S.C. § 1396i-8(k)(6), or was not covered by the State's Medicaid program. This conduct is referred to below as the "Covered Conduct."

G. This Settlement Agreement is made in compromise of disputed claims. This Agreement is neither an admission of liability by Defendants, nor a concession by the State that its allegations are not well founded.

H. To avoid the delay, expense, inconvenience, and uncertainty of protracted litigation of the above causes of action, the Parties mutually desire to reach a full and final settlement as set forth below.

### III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants and obligations set forth in this Agreement, and for good and valuable consideration as stated herein, the Parties agree as follows:

I. Defendants collectively shall pay to the United States and the Medicaid Participating States (as defined in sub-paragraph (c) below) the sum of sixty-seven million dollars (\$67,000,000), plus accrued interest on that amount at the rate of 2.125%.

per annum commencing on November 19, 2015, and continuing until and including the day payment is made under this Agreement (the "Settlement Amount"). The Settlement Amount shall constitute a debt immediately due and owing to the United States and the Medicaid Participating States on the Effective Date of the Federal Settlement Agreement, and subject to the terms of this Agreement. This debt shall forever be discharged by payments to the United States and the Medicaid Participating States, under the following terms and conditions:

(a) Defendants collectively shall pay to the United States the sum of \$62,645,000, plus accrued interest on that amount at the rate of 2.125% per annum commencing on November 19, 2015 and continuing until and including the date of payment ("Federal Settlement Amount"). The Federal Settlement Amount shall be paid pursuant to the terms of the Federal Settlement Agreement.

(b) Defendants collectively shall pay to the Medicaid Participating States the sum of \$4,355,000, plus accrued interest on that amount at the rate of 2.125% per annum commencing on November 19, 2015 and continuing until and including the date of payment ("Medicaid State Settlement Amount"), subject to the non-participating state deduction provision of sub-paragraph (d) below ("Medicaid Participating State Settlement Amount"), no later than seven (7) business days after the Effective Date of the Federal Settlement Agreement. The Medicaid Participating State Settlement Amount shall be paid by electronic funds transfer to the New York State Attorney General's National Global Settlement Account pursuant to written instructions from the State Negotiating Team ("State Team"), which written instructions shall be delivered to counsel for Defendants.

(c) Defendants shall execute a State Settlement Agreement with any State that executes such an Agreement in the form to which Defendants and the State Team have agreed, or in a form otherwise agreed to by Defendants and an individual State. The State shall constitute a Medicaid Participating State provided this Agreement is fully executed by the State and delivered to Defendants' attorneys within 45 days of receiving this Agreement. If this condition is not satisfied within 45 days, Defendants' offer to resolve this matter with the individual State shall become null and void absent written agreement between counsel for Defendants and the State Team to extend the 45 day period.

(d) The total portion of the amount paid by Defendants in settlement for the Covered Conduct for the State is \$1,285,083.32, consisting of a portion paid to the State under this Agreement and another portion paid to the United States as part of the Federal Settlement Agreement. The individual portion of the Medicaid State Settlement Amount allocated to the State under this Agreement is the sum of \$803,891.80, plus applicable interest (the "State Amount"). If the State does not execute this Agreement within 45 days of receiving this Settlement Agreement, the State Amount shall be deducted from the Medicaid State Settlement Amount and shall not be paid by Defendants, absent written agreement between counsel for Defendants and the State Team to extend the time period for executing this Agreement.

2. The State agrees to promptly dismiss with prejudice any state law claims that the State has the authority to dismiss currently pending against Defendants in State or Federal Courts for the Covered Conduct including any supplemental state law claims asserted in the Civil Action. The State further agrees to dismiss without prejudice all

other claims against the Released Entities (as defined below) in the Civil Action.

Contingent upon the receipt of its respective State Amount, the State, if served with the Civil Action and liable to pay a Relator's share, agrees to pay the Relator the amount of \$136,661.61, plus applicable interest. This amount is to be paid through the State Team and has been addressed via side letter with the Relator in the Civil Action.

3. Subject to the exceptions in Paragraph 4 below, in consideration of the obligations of Defendants set forth in this Agreement, and conditioned upon receipt by the State of its share of the Medicaid State Settlement Amount, the State agrees to release each defendant together with its current and former direct and indirect parent corporation 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 owners; and the predecessors, successors, transferees, and assigns of any of them (collectively, the "Released Entities"); from any civil or administrative monetary causes of action that the State has for any claims submitted or caused to be submitted to the State Medicaid Program as a result of the Covered Conduct. The payment of the Medicaid State Settlement Amount fully discharges the Released Entities from any obligation to pay Medicaid restitution, Medicaid damages, Medicaid civil fines, and/or Medicaid civil penalties, to the State for the Covered Conduct.

4. Notwithstanding any term of this Agreement, the State specifically does not release any person or entity from any of the following liabilities:

(a) any criminal, civil, or administrative liability arising under state revenue codes;

(b) any criminal liability not specifically released by this Agreement;

(c) any civil or administrative liability that any person or entity has or may have to the State or to individual consumers or state program payors under any statute, regulation or rule not expressly covered by the release in Paragraph 3 above, including but not limited to, any and all of the following claims: (i) state or federal antitrust violations; or (ii) claims involving unfair and/or deceptive acts and practices and/or violations of consumer protection laws;

(d) any liability to the State for any conduct other than the Covered Conduct;

(e) any liability which may be asserted on behalf of any other payors or insurers, including those that are paid by the State's Medicaid program on a capitated basis;

(f) any liability based upon obligations created by this Agreement;

(g) except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusions from the State's Medicaid program;

(h) any express or implied warranty claims or other liability for defective or deficient products and services provided by Defendants;

(i) any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct;

(j) any liability of individuals; or

(k) any liability based on a failure to deliver goods or services due.

5. The State expressly reserves all rights to institute, direct, or to maintain any administrative action seeking exclusion against each defendant and/or its officers, directors, and employees from the State's Medicaid Program (as defined in 42 U.S.C. 1320a-7b(f) under 1320a-7(a) (mandatory exclusion) or 42 U.S.C. 1320a-7(b) or 42 U.S.C. 1320a-7a (permissive exclusion)).

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

7. In consideration of the obligations of the State set forth in this Agreement, each defendant waives and discharges the State, its agencies, employees, and agents, from any causes of action (including claims for attorneys' fees, costs, and expenses of every kind and however denominated) that Defendants have against the State, its agencies, employees, and agents arising from the State's investigation and prosecution of the Covered Conduct.

8. The amount that Defendants must pay to the State pursuant to Paragraph III.1. above will not be decreased as a result of the denial of any claims for payment now being withheld from payment by the State's Medicaid program, or any other state payor, for the Covered Conduct; and, if applicable, Defendants agree not to resubmit to the State's Medicaid program or any other state payor, any previously denied claims, which denials were based on the Covered Conduct, and agrees to withdraw the appeal of, or not to appeal, or cause the appeal of any such denials of claims.

9. Defendants shall not seek payment for any of the claims for reimbursement to the State's Medicaid Program covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors.



10. Defendants expressly warrant that they have reviewed their respective financial conditions and that they are currently solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(i)(I), and shall remain solvent following payment of the Settlement Amount and compliance with this Agreement.

11. The Parties each represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

12. Each defendant agrees to cooperate fully and truthfully with any State investigation of individuals or entities not released in this Agreement relating to the Covered Conduct. More specifically, upon reasonable notice, each defendant shall encourage, and agrees not to impair, the cooperation of its directors, officers, employees or agents, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Each defendant further agrees to furnish to the State, upon request, complete and unredacted copies of all non-privileged documents including, but not limited to, reports, memoranda of interviews, and records in their possession, custody or control, concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

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

14. Except as otherwise stated in this Agreement, this Agreement is intended to be for the benefit of the Parties only and by this instrument the Parties do not release any liability against any other person or entity.

15. Nothing in this Agreement constitutes an agreement by the State concerning the characterization of the amounts paid hereunder for purposes of the State's revenue code.

16. In addition to all other payments and responsibilities under this Agreement, Defendants agree to pay all reasonable expenses and travel costs of the State Team, including reasonable consultant fees and expenses. Defendants will pay this amount by separate check made payable to the National Association of Medicaid Fraud Control Units, after the Medicaid Participating States execute their respective Agreements, or as otherwise agreed by the Parties.

17. This Agreement is governed by the laws of the State and venue for addressing and resolving any and all disputes relating to this Agreement shall be the state courts of appropriate jurisdiction of the State.

18. The undersigned signatories for each defendant represent and warrant that they are each authorized as a result of appropriate corporate action to execute this Agreement. The undersigned State signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement on behalf of the State through their respective agencies and departments.

19. The Effective Date of this Agreement shall be the date of signature of the last signatory to this Agreement. Facsimiles of signatures shall constitute acceptable binding signatures for purposes of this Agreement.

20. This Agreement shall be binding on all successors, transferees, heirs, and assigns of the Parties.


21. This Agreement constitutes the complete agreement among the Parties with respect to this matter and shall not be amended except by written consent of the Parties.

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

STATE OF CALIFORNIA


KAMALA D. HARRIS  
Attorney General of the State of California.

Original Signed By:

BY:  \_\_\_\_\_  
Raymond J. Liddy  
Deputy Attorney General  
Bureau of Medi-Cal Fraud and Elder Abuse  
California Department of Justice  
1455 Frazee Rd, Ste. 315  
San Diego, CA 92108

Date: 5/19/16

Original Signed By:

BY:  \_\_\_\_\_  
Jennifer Kent  
Director  
CA Department of Health Care Services  
MS 0000  
P.O. Box 997413  
Sacramento, CA 95899-7413

Date: 5/19/16

OSI PHARMACEUTICALS LLC

DATED: 6/6/16

Original Signed By:  
BY: \_\_\_\_\_

MATTHEW O'CONNOR  
GEOFFREY HOBART  
SARAH A. FRANKLIN

Counsel for OSI Pharmaceuticals, LLC

DATED: 6/6/16

Original Signed By:  
\_\_\_\_\_

Secretary, OSI Pharmaceuticals, LLC

GENENTECH, INC.

DATED: 6/6/16

BY: Original Signed By:  
[Signature]  
PAUL EKALB  
DAVID ANDERSON  
JOSHUA HILL

DATED: \_\_\_\_\_

BY: Original Signed By:  
\_\_\_\_\_  
HANNAH WILLIAMS  
Counsel for Genentech, Inc.

GENENTECH, INC.

DATED: \_\_\_\_\_

BY: Original Signed By:  
PAUL E. KALB,  
DAVID ANDERSON  
JOSHUA HILL

DATED: 6/6/16

BY: Original Signed By:  
HANNAH WILLIAMS  
Counsel for Genentech, Inc.