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"), the Office of Personnel Management ("OPM"), which administers the Federal Employees Health Benefits Program ("FEHBP"), and the Defense Health Agency ("DHA"), acting on behalf of the TRICARE Program, (collectively, the "United States"), Genentech, Inc. ("Genentech") and OSI Pharmaceuticals, LLC (together referred to as "Defendants"), and Brian Shields ("Relator") (hereinafter collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

A. Genentech is a Delaware corporation with its principal place of business in South San Francisco. OSI Pharmaceuticals, Inc. was a Delaware corporation with its principal place of business in New York. In June 2010, OSI Pharmaceuticals, Inc. was acquired by Astellas US Holding, Inc. and, in March 2011, was converted to a Delaware limited liability company, OSI Pharmaceuticals LLC ("OSI"). 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 *qui tam* 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").

C. The United States alleges that Defendants caused to be submitted claims for payment to the Medicare Program ("Medicare"), Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1; the TRICARE Program ("TRICARE"), 10 U.S.C. §§ 1071-1110b; the FEHBP, 5 U.S.C. §§ 8901-8914; and the Medicaid Program ("Medicaid"), 42 U.S.C. §§ 1396-1396w-5 (collectively the "Federal Health Care Programs").

D. Tarceva treats non-small cell lung cancer ("NSCLC") by targeting the epidermal growth factor receptor ("EGFR") 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.

E. The United States 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 EFGR

mutation or unless they had never smoked. As a result, Defendants knowingly caused false or fraudulent claims for Tarceva to be submitted to, or caused purchases by, Federal Health Care Programs for Tarceva to treat NSCLC, as a first line of therapy, in current or former smokers classified as ECOG PS 0 or 1 who did not have a known EFGR 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. § 1396r-8(k)(6), or was not covered by the United States and state Medicaid programs. That conduct is referred to below as the "Covered Conduct."

F. Defendants have entered into, or will enter into, separate settlement agreements, described in Paragraph 1b below, with certain states in settlement of the Covered Conduct (hereinafter referred to as the "Medicaid State Settlement Agreements"). States with which Defendants execute a Medicaid State Settlement Agreement shall be referred to as "Medicaid Participating States."

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 United States that its claims are not well founded.

H. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Agreement and to Relator's reasonable expenses, attorneys' fees, and costs.

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 Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Defendants collectively shall pay to the United States and the Medicaid Participating States, the sum of Sixty-Seven Million Dollars ($67,000,000.00), plus interest at the rate of 2.125 percent per annum from November 19, 2015, and continuing until and including the date of payment (the "Settlement Amount"), pursuant to the following terms:

(a) Defendants collectively shall pay to the Medicaid Participating States the sum of $4,355,000, plus interest at the rate of 2.125 percent per annum from November 19, 2015, and continuing until and including the date of payment (the "Medicaid State Settlement Amount"). The Medicaid State Settlement Amount shall be paid by electronic funds transfer pursuant to written instructions from the National Association of Medicaid Fraud Control Units ("NAMFCU") under the terms and conditions of the Medicaid State Settlement Agreements that Defendants will enter into with the Medicaid Participating States.

(b) Defendants collectively shall pay to the United States the sum of $62,645,000, plus accrued interest at the rate of 2.125 percent per annum from November 19, 2015, and continuing until and including the date of payment as set forth above (the "Federal Settlement Amount"). The Federal Settlement Amount shall be paid by electronic funds transfer no later than seven (7) business days after the Effective Date of this Agreement pursuant to written instructions from the Civil Division of the United States Department of Justice.

2. Conditioned upon the United States receiving the full Federal Settlement Amount from Defendants, and as soon as feasible after receipt, the United States shall pay $10,649,650 to Relator by electronic funds transfer.

3. Subject to the exceptions in Paragraph 8 (concerning excluded claims) below, and conditioned upon Defendants' full payment of the Settlement Amount, the United States releases 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, from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; any statutory provision creating a cause of action for civil damages or civil penalties which the Civil Division of the Department of Justice has actual or present authority to assert and compromise pursuant to under 28 C.F.R. Pt. 0, Subpart I, 0.45(d); or the common law theories for fraud, payment by mistake, and unjust enrichment.

4. Conditioned upon Defendants' full payment of the Settlement Amount, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, releases each Defendant together with its current and former Parents; its and their affiliates, direct and indirect subsidiaries, brother and sister corporations, and divisions; and its and their respective current and former owners, officers, directors, employees, and agents, individually or collectively; and the predecessors, successors, transferees and assigns of

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