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# OSI Pharmaceuticals Submits Supplemental New Drug Application to the FDA for Tarceva as a First-Line Maintenance Therapy in Advanced Non-Small Cell Lung Cancer

## -- Roche Submits Marketing Authorization Application for Approval of Tarceva as a First-line Maintenance Therapy in Europe --

MELVILLE, N.Y. & SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Mar. 19, 2009-- OSI Pharmaceuticals, Inc. (Nasdaq: OSIP) and Genentech, Inc., (NYSE: DNA) today announced that OSI submitted a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) for the use of Tarceva® (erlotinib) as a first-line maintenance therapy for people with advanced non-small cell lung cancer (NSCLC) who have not progressed following first-line treatment with platinum-based chemotherapy. Additionally, the Companies announced that Roche, their international collaborator for Tarceva, filed an application in Europe with the European Medicines Agency (EMEA).

"If approved, Tarceva will be the first EGFR targeted and oral therapy available as a first-line maintenance treatment for people with NSCLC, which we believe is an important advancement in the treatment of lung cancer," stated Colin Goddard , Ph.D., Chief Executive Officer of OSI Pharmaceuticals.

"The FDA application reflects our goal of extending the time people with advanced lung cancer live without their disease progressing following initial treatment with chemotherapy," said Hal Barron , M.D., Genentech's senior vice president, Development and chief medical officer.

Both the U.S. and EU submissions are based on a pivotal Phase III placebo-controlled, randomized, double-blind trial known as SATURN. In November 2008, OSI, Genentech and Roche announced that SATURN met its primary endpoint and showed that Tarceva significantly extended the time patients with advanced NSCLC lived without their cancer getting worse (progression-free survival or PFS) when given immediately following initial treatment with platinum-based chemotherapy, compared to placebo. There were no new or unexpected safety signals in the study and adverse events were consistent with those observed in previous NSCLC clinical trials evaluating Tarceva.

The SATURN data will be presented at the 45th Annual Meeting of the American Society of Clinical Oncology being held May 29-June 2, 2009 in Orlando, Fla. Overall survival data, a secondary endpoint of the study, are expected in the second half of 2009 and will be part of the FDA review process.

**Additional Information about SATURN**

The SATURN study, conducted by Roche, enrolled 889 patients with advanced NSCLC at approximately 160 sites worldwide. Patients were treated with at least four cycles of standard first-line platinum-based chemotherapy and were then randomized to Tarceva or placebo if their cancer did not progress. The primary endpoint of the study was progression-free survival. Secondary endpoints included overall survival, safety and an evaluation of exploratory biomarkers.

**About Lung Cancer**

According to the American Cancer Society (ACS), lung cancer is the single largest cause of cancer death among men and women in the U.S. and nearly 162,000 Americans died from the disease in 2008. Most people with lung cancer are diagnosed with advanced stage disease that cannot be surgically removed or has spread to other parts of the body. The majority of people with advanced lung cancer survive less than one year. NSCLC is the most common type of lung cancer.

**About Tarceva**

Tarceva is a small molecule designed to target the EGFR pathway, which is one of the factors critical to cell growth in NSCLC and pancreatic cancers. Tarceva is designed to inhibit the tyrosine kinase activity of the EGFR signaling pathway inside the cell.

Tarceva is FDA-approved for use as a monotherapy in patients with locally advanced or metastatic NSCLC whose disease has progressed after one or more courses of chemotherapy. Results from two, multicenter, placebo-controlled, randomized, Phase III trials conducted in first-line patients with locally advanced or metastatic NSCLC showed no clinical benefit with the concurrent administration of Tarceva with platinum-based chemotherapy (carboplatin and paclitaxel or gemcitabine and cisplatin) and its

use is not recommended in that setting.

Tarceva is also approved in combination with gemcitabine for the treatment of patients who have not received previous chemotherapy for locally advanced pancreatic cancer, pancreatic cancer that cannot be surgically removed or pancreatic cancer that has spread to distant body organs.

**Tarceva Safety**

In clinical studies, there were infrequent reports of serious lung injuries similar to Interstitial Lung Disease (ILD)-like events including deaths. Liver and/or kidney problems (including deaths) have been reported in some patients taking Tarceva. Patients receiving Tarceva plus gemcitabine were more likely to experience bleeding and clotting problems such as heart attack or stroke. Women should avoid becoming pregnant and avoid breastfeeding while taking Tarceva. Patients taking Tarceva have experienced new or worsening skin rash; serious or ongoing diarrhea, nausea, loss of appetite, or vomiting; new or worsening shortness of breath or cough; fever; eye irritation. Patients should stop smoking while taking Tarceva. Rash and diarrhea were the most common side effects associated with Tarceva in the non-small cell lung cancer clinical study. Fatigue, rash, nausea, loss of appetite, and diarrhea were the most common side effects associated with Tarceva plus gemcitabine therapy in the pancreatic cancer clinical study.

For full prescribing information, please call 1-877-TARCEVA or visit http://www.tarceva.com.

**About OSI Pharmaceuticals**

OSI Pharmaceuticals is committed to "shaping medicine and changing lives" by discovering, developing and commercializing high-quality, novel and differentiated personalized medicines designed to extend life and improve the quality of life for patients with cancer and diabetes/obesity. For additional information about OSI, please visit http://www.osip.com.

**About Genentech**

Founded more than 30 years ago, Genentech is a leading biotechnology company that discovers, develops, manufactures and commercializes medicines for patients with significant unmet medical needs. The company has headquarters in South San Francisco, California and is listed on the New York Stock Exchange under the symbol DNA. For additional information about the company, please visit http://www.gene.com.

**OSI Safe Harbor Statement**

*This news release contains forward-looking statements. These statements are subject to known and unknown risks and uncertainties that may cause actual future experience and results to differ materially from the statements made. Factors that might cause such a difference include, among others, OSI's and its collaborators' abilities to effectively market and sell Tarceva and to expand the approved indications for Tarceva, OSI's ability to protect its intellectual property rights, safety concerns regarding Tarceva, competition to Tarceva and OSI's drug candidates from other biotechnology and pharmaceutical companies, the completion of clinical trials, the effects of FDA and other governmental regulation, including pricing controls, OSI's ability to successfully develop and commercialize drug candidates, and other factors described in OSI Pharmaceuticals' filings with the Securities and Exchange Commission.*

**Genentech Safe Harbor Statement**

*This press release contains forward-looking statements regarding the potential for Tarceva and approval for Tarceva in the first-line maintenance setting for NSCLC. Such statements are predictions and involve risks and uncertainties such that actual results may differ materially. Actual results may be affected by a number of factors including, but not limited to, unexpected safety, efficacy or manufacturing issues, the need for additional data, data analysis or clinical studies, NDA preparation, FDA actions or delays, failure to obtain or maintain FDA approval, competition, pricing, reimbursement, the ability to supply product, product withdrawals and new product approvals and launches, and intellectual property or contract rights. Please also refer to the risk factors described in Genentech's periodic reports filed with the Securities and Exchange Commission. Genentech disclaims, and does not undertake, any obligation to update or revise any forward-looking statement in this press release.*

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