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Phase III Study (SATURN) Showed Tarceva Improved Progression-Free Survival as a First-Line Maintenance Therapy for Advanced Non-Small Cell Lung Cancer

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SOUTH SAN FRANCISCO, Calif. & MELVILLE, N.Y.--(BUSINESS WIRE)--Nov. 7, 2008--Genentech, Inc. (NYSE:DNA) and OSI Pharmaceuticals, Inc. (Nasdaq:OSIP) today announced that a global Phase III study (SATURN) met its primary endpoint and showed Tarceva® (erlotinib) significantly extended the time patients with advanced non-small cell lung cancer (NSCLC) lived without their cancer getting worse 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 study results are being fully analyzed and the data will be submitted for presentation at a future medical meeting. OSI, Genentech and Roche will discuss next steps for a potential new indication for Tarceva with the U.S. Food and Drug Administration (FDA) and European Health Authorities.

"We believe that Tarceva as a once-a-day oral therapy, which has a well-established safety profile, may be well-suited as a maintenance therapy in the first-line setting following chemotherapy," said Gabriel Leung, President, OSI Oncology. "We are excited about the prospect that for the first time patients may have a treatment alternative that is different from traditional chemotherapy and extends the time patients live without their cancer progressing following initial treatment."

"We are pleased by the findings as they represent another step forward in our hopes of providing more options to patients throughout their battle with lung cancer," said Hal Barron, M.D., Genentech's senior vice president, Development and chief medical officer.

Tarceva is currently approved as a second-line treatment for patients with advanced NSCLC, who have progressed following treatment with at least one prior chemotherapy regimen, based on a 37 percent improvement in overall survival compared to placebo (hazard ratio 0.73).

"There is an unmet need for treatments that can be used as early as possible following initial treatment of NSCLC and the results from the SATURN study provide a strong rationale for introducing Tarceva as a maintenance therapy in this difficult to treat disease," said Professor F. Capuzzo, M.D., Istituto Clinico Humanitas IRCCS, Milan, Italy and lead investigator of the SATURN study.

According to the American Cancer Society (ACS) lung cancer is the single largest cause of cancer deaths among men and women in the United States and is responsible for nearly 30 percent of cancer deaths. The ACS estimates that in 2008 more than 215,000 Americans will be diagnosed with lung cancer and 162,000 will die of the disease. NSCLC is the most common type of lung cancer.

About SATURN

SATURN is a placebo-controlled, randomized, double-blind, Phase III study conducted by Roche that 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 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

There have been infrequent reports of serious Interstitial Lung Disease (ILD)-like events, including fatalities, in patients receiving Tarceva for treatment of NSCLC, pancreatic cancer or other advanced solid tumors. Cases of hepatic failure, hepatorenal syndrome, acute renal failure (all including fatalities), and renal insufficiency have been reported during use of Tarceva. When receiving Tarceva therapy, women should be advised against becoming pregnant or breastfeeding. Tarceva is pregnancy category D. The most common adverse reactions in patients with NSCLC receiving Tarceva monotherapy were rash and diarrhea. The most common adverse reactions in patients with pancreatic cancer receiving Tarceva plus gemcitabine were fatigue, rash, nausea, anorexia, and diarrhea.

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

About OSI Pharmaceuticals

OSI Pharmaceuticals is committed to "shaping medicine and changing lives" by discovering, developing and commercializing high-quality and novel pharmaceutical products designed to extend life and/or improve the quality of life for patients with cancer and diabetes/obesity. The Company's oncology programs are focused on developing molecular targeted therapies designed to change the paradigm of cancer care. OSI's diabetes/obesity efforts are committed to the generation of novel, targeted therapies for the treatment of type 2 diabetes and obesity. OSI's flagship product, Tarceva® (erlotinib), is the first drug discovered and developed by OSI to obtain FDA approval and the only EGFR inhibitor to have demonstrated the ability to improve survival in both NSCLC and pancreatic cancer patients in certain settings. OSI markets Tarceva through partnerships with Genentech, Inc. in the United States and with Roche throughout the rest of the world. For additional information about OSI, please visit (http://www.osip.com).

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.

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, the results from, and the ability to complete, clinical trials, the FDA review process and other governmental regulation, OSI's and its collaborators' abilities to successfully develop and commercialize drug candidates, competition from other pharmaceutical companies, the ability to effectively market products, and other factors described in OSI Pharmaceuticals' filings with the Securities and Exchange Commission.

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