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New Data from Phase III SATURN Study Showed Tarceva Improved Overall Survival When Used Immediately After Initial Chemotherapy in Patients with Advanced Non-Small Cell Lung Cancer

MELVILLE, N.Y. & SOUTH SAN FRANCISCO, Calif., Jul 13, 2009 (BUSINESS WIRE) -- OSI Pharmaceuticals, Inc. (NASDAQ: OSIP) and Genentech, Inc. today announced that SATURN, a pivotal Phase III study of Tarceva(R) (erlotinib), met a key secondary endpoint of extending overall survival in patients with advanced non-small cell lung cancer (NSCLC) who received Tarceva immediately after initial chemotherapy. A statistically significant improvement in overall survival was seen in this pre-planned final analysis of the total patient population. The new data will be presented during the 13th World Conference on Lung Cancer to be held July 31 to August 4, 2009 in San Francisco.

Treating patients immediately following first-line chemotherapy versus waiting for the cancer to grow or spread before giving additional treatment represents a new approach in advanced NSCLC.

"This study has now not only confirmed that immediate treatment with Tarceva after initial chemotherapy delayed the progression of disease, but also importantly helped patients in the study live longer," said Professor Federico Cappuzzo, M.D., Istituto Clinico Humanitas IRCCS, Milan and principal investigator of the SATURN study. "This is good news for doctors and their patients since advanced lung cancer is one of the most challenging cancers to treat and is often associated with a very short life expectancy."

The overall survival data will be submitted to the U.S. Food and Drug Administration (FDA) to support the supplemental New Drug Application (sNDA) for use of Tarceva as a first-line maintenance treatment for patients with advanced NSCLC that was submitted on March 17, 2009. The FDA Prescription Drug User Fee Act (PDUFA) review date will be on or about January 18, 2010.

Additionally, Roche, OSI's international collaborator for Tarceva, will submit the overall survival data to the European Medicines Agency (EMEA) to support the application for use of Tarceva as a first-line maintenance treatment submitted in March 2009.

The U.S. and EU submissions were based on positive data from SATURN that were presented at the 45th Annual Meeting of the American Society of Clinical Oncology (ASCO) on May 31, 2009 in Orlando, Fla. SATURN met its primary endpoint and showed patients with advanced NSCLC who received Tarceva as a first-line maintenance treatment had a 41 percent improvement in the time they lived without the disease advancing (progression-free survival or PFS) compared to placebo (hazard ratio=0.71; 29 percent reduction in the risk of cancer progression or death). The safety results were consistent with what has been seen previously and there were no new or unexpected safety signals in the study. The most commonly reported adverse events in patients who received Tarceva were rash (49 percent, 213/438) and diarrhea (20 percent, 88/438).

According to the American Cancer Society, lung cancer is the leading cause of cancer death in the United States. In 2009, approximately 159,000 Americans will die from the disease. Most people are diagnosed with advanced stage disease and only 15 percent survive five years.

About SATURN

SATURN is an international, 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 four cycles of standard first-line platinum-based chemotherapy and were then randomized to Tarceva or placebo if the cancer did not progress. The primary endpoint of the study was progression-free survival in the overall population, as determined by investigators, and was defined as the length of time from randomization to disease progression or death from any cause. The co-primary endpoint was PFS in patients with EGFR-positive tumors by IHC. Secondary endpoints included overall survival, safety and an evaluation of exploratory biomarkers, including EGFR mutations and K-ras mutations.

About Tarceva

Tarceva is a once-a-day pill that targets the EGFR pathway. Tarceva is designed to inhibit the tyrosine kinase activity of the EGFR signaling pathway inside the cell, one of the critical growth factors in NSCLC and pancreatic cancers. Tarceva is indicated as a monotherapy for 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.

In pancreatic cancer, Tarceva is indicated in combination with gemcitabine for the first-line treatment of patients with 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 deaths in patients taking Tarceva. Serious side effects (including deaths) in patients taking Tarceva include liver and/or kidney problems; gastrointestinal (GI) perforations (the development of a hole in the stomach, small intestine, or large intestine); and severe blistering skin reactions including cases similar to Stevens-

Johnson syndrome. Patients taking Tarceva plus gemcitabine were more likely to experience bleeding and clotting problems such as heart attack or stroke. Eye irritation and damage to the cornea have been reported in patients taking Tarceva. Women should avoid becoming pregnant and avoid breastfeeding while taking Tarceva. Patients should call their doctor right away if they have these signs or symptoms: new or worsening skin rash; serious or ongoing diarrhea, nausea, loss of appetite, vomiting or stomach pain; new or worsening shortness of breath or cough; fever; eye irritation. 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 targeted 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 to treat patients with serious or life-threatening medical conditions. The company, a wholly-owned member of the Roche Group, has headquarters in South San Francisco, Calif. 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 andpharmaceutical 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.

SOURCE: OSI Pharmaceuticals, Inc. and Genentech, Inc.

OSI:
Media/ Investor:
Kathy Galante, 631-962-2043
Media: Kim Wittig, 631-962-2135
or
Genentech:
Media:
Charlotte Arnold, 650-467-6800
Advocacy:
Kristin Olson, 650-467-9129
Investor:

Susan Morris, 650-225-6334
Karl Mahler 011 41 61 687 85 03