

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

MELVILLE, N.Y., Aug 01, 2009 (BUSINESS WIRE) -- OSI Pharmaceuticals, Inc. (NASDAQ: OSIP) today announced further results from the Phase III SATURN study showing that Tarceva(R) (erlotinib) extended the survival of patients with advanced non-small cell lung cancer (NSCLC) when used as single agent, maintenance therapy in patients who did not progress following first-line treatment with platinum-based chemotherapy. As previously announced, the safety results in this study were consistent with what has been seen previously and there were no new or unexpected safety signals. Overall survival was a key secondary endpoint of the study and these new data were presented today at the 13th World Conference on Lung Cancer being held in San Francisco.

"Based on the data presented today, Tarceva is the first oral cancer therapy to show a survival benefit in the first-line maintenance NSCLC setting. Assuming approval, when used immediately after chemotherapy, Tarceva will provide a new, convenient, non-chemotherapy treatment option for patients - allowing doctors to continue treating a patient's disease without exposing them to the continuous burden and lifestyle constraints of long-term chemotherapy," stated Gabe Leung, President, Pharmaceutical Business of OSI Pharmaceuticals.

The study showed that patients with NSCLC treated with Tarceva had a 23 percent improvement in overall survival compared with patients who received placebo (hazard ratio=0.81; p-value=0.0088). The hazard ratio, which assesses risk in the overall trial population, is widely recognized as the best measure of overall benefit in large randomized clinical trials. A hazard ratio of less than one for survival indicates a reduced risk of death. The median survival (a single point estimate of benefit) for patients receiving Tarceva was 12 months versus a median survival of 11 months for patients receiving placebo.

The study confirmed that a broad spectrum of patients with advanced NSCLC experienced a survival benefit from Tarceva. Specific analysis of patients in the study whose tumors were confirmed not to have genetic mutations in their epidermal growth factor receptor (EGFR "wild-type") showed that this group experienced a 30 percent improvement in survival (hazard ratio = 0.77; p-value = 0.0243). The majority of patients with NSCLC are EGFR wild-type. Full data analysis for various sub-groups is still on-going. However, available data also showed that the hazard ratio for overall survival in patients with tumors expressing the EGFR gene by Immunohistochemistry (IHC) was also 0.77 (p-value = 0.0063).

As presented previously, the hazard ratio for progression-free survival (the time patients live without their disease worsening) in patients with EGFR mutations was 0.10 (p-value <0.0001). Overall survival for this patient sub-group is still immature with the median survival not yet being reached in patients with EGFR mutations receiving Tarceva. Determination of the overall survival benefit in this sub-group was further confounded by the fact that two-thirds of the patients with EGFR mutations who received placebo crossed over to receive Tarceva or another EGFR therapy. An ongoing Phase III trial evaluating how Tarceva compared to traditional chemotherapy for first-line treatment in patients whose tumors had an EGFR mutation is expected to provide more insight. This study, called EURTAC, is a collaboration between Roche and the Spanish Lung Cancer Group.

"The overall SATURN results continue to reinforce our belief that Tarceva therapy for NSCLC patients whose cancers have an EGFR mutation has the potential to result in a major advancement in personalized medicine using targeted therapies - even as they continue to demonstrate the broad-based benefit of Tarceva therapy in treating the overall NSCLC population," stated David Epstein, Senior Vice President, Oncology Research at OSI Pharmaceuticals.

Additional analysis on survival in other patient subsets and in patients with specific biomarkers is still on-going and will be presented at future meetings.

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 (EMA) to support the application for use of Tarceva as a first-line maintenance treatment submitted in March 2009.

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 study 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). PFS 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.

The safety results were consistent with what has been previously seen 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).

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>.

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.

SOURCE: OSI Pharmaceuticals, Inc.

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