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Phase III Study Showed Tarceva in Combination with Avastin as First-Line Maintenance Therapy Improved Progression-Free Survival in Advanced Lung Cancer

-- Study is Second Positive Phase III Trial of Tarceva as First-Line Maintenance Therapy --

MELVILLE, N.Y.--(BUSINESS WIRE)-- OSI Pharmaceuticals, Inc. (NASDAQ: OSIP) announced today that its U.S. partner for Tarceva® (erlotinib), Genentech, Inc., informed OSI that a Genentech conducted Phase III study, ATLAS, was stopped early on the recommendation of an independent data safety monitoring board. A pre-planned interim analysis showed that combining Tarceva and Avastin® (bevacizumab) significantly extended the time patients lived without their disease advancing, as defined by progression-free survival (PFS), compared with Avastin plus placebo. Genentech further informed OSI that a preliminary safety analysis showed adverse events were consistent with previous Avastin or Tarceva studies as well as trials evaluating the two medicines together, and no new safety signals were observed. Data will be submitted for presentation at a future medical meeting.

An earlier study, SATURN, showed Tarceva delayed disease progression when given as a single agent immediately following treatment with chemotherapy, compared to placebo. In ATLAS, patients were initially treated with Avastin plus chemotherapy followed by the addition of Tarceva to Avastin in the maintenance phase.

About ATLAS

ATLAS is a global, multicenter, randomized, double-blind, placebo-controlled study that enrolled 1,157 patients with locally advanced, recurrent or metastatic non-small cell lung cancer (NSCLC). In order to evaluate patients who are often excluded from Avastin-based clinical trials, patients with treated brain metastases, tumors of squamous cell histology that were not centrally located in the lung, and those taking blood-thinning medications were eligible for this trial. Patients were initially treated with four cycles of Avastin in combination with the investigators' choice of platinum-based chemotherapy regimens (carboplatin/gemcitabine, carboplatin/paclitaxel, carboplatin/docetaxel, cisplatin/vinorelbine, cisplatin/docetaxel or cisplatin/gemcitabine). If their cancer did not progress and they did not experience significant toxicity, patients were then randomized (n=768) to receive maintenance therapy with Avastin plus Tarceva or Avastin plus placebo until disease progression. The study's primary endpoint of PFS, as determined by investigators, was defined as the length of time from randomization to disease progression or death from any cause. PFS assessment began from the start of the maintenance phase of the study after initial treatment with four cycles of Avastin and chemotherapy. Secondary endpoints included overall survival, incidence of all adverse events and selected Grade 3 or greater adverse events and incidence of treatment discontinuation for reasons other than disease progression. The ATLAS study was funded by Genentech and Roche. Under terms of the Tripartite Agreement between OSI, Genentech and Roche, OSI may be required to make certain retrospective funding payments for the ATLAS study depending upon, amongst other things, potential submission of data to regulatory authorities.

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 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 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 for Tarceva, 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 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 non-small cell lung cancer 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.

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 completion of 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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