(osi) pharmaceuticals

OSI Pharmaceuticals Launches Study of Tarceva(R) as Adjuvant Treatment for Non-Small Cell Lung Cancer

MELVILLE, N.Y.--(BUSINESS WIRE)--Sept. 21, 2006--OSI Pharmaceuticals, Inc. (Nasdaq: OSIP) announced today that it has begun a Phase III clinical trial of Tarceva® (erlotinib) as a targeted adjuvant therapy in patients who have undergone surgery for non-small cell lung cancer (NSCLC) with EGFR-positive tumors. An oral, once-daily medication, Tarceva is currently indicated for the treatment of patients with locally advanced or metastatic NSCLC after failure of at least one chemotherapy regimen, and in combination with gemcitabine chemotherapy for the first-line treatment of locally advanced unresectable or metastatic pancreatic cancer. OSI is developing and commercializing Tarceva in collaboration with Genentech, Inc. and Roche.

"We are committed to evaluating the potential benefit of treating patients with Tarceva as a targeted adjuvant therapy after surgery, while gaining a better understanding of how testing for EGFR in tumor tissue may help identify those patients likely to derive the most significant benefit from Tarceva therapy," said Gabriel Leung, President, (OSI) Oncology. "This is highly relevant in patients with early stages of lung cancer, whose tumor tissues are more likely to be available for testing and whose disease has more potential to be curable."

OSI received a Special Protocol Assessment (SPA) from the U.S. Food and Drug Administration (FDA) for the study. In the letter providing for the SPA, the FDA stated that the design and planned analyses of the clinical study adequately address the objectives and are sufficient to provide the data necessary to support a label expansion submission, if the study is successful.

Study Design

The international, multi-center, placebo-controlled study will enroll approximately 945 patients. The primary objective is to evaluate the effectiveness of adjuvant therapy with Tarceva in prolonging disease free survival. Secondary objectives of the study are to compare overall survival between study arms, evaluate the safety of adjuvant Tarceva therapy, and explore the prognostic value of EGFR-related biomarkers that may be associated with clinical outcomes following treatment with Tarceva.

The study will enroll patients with surgically removed Stage IB-IIIA NSCLC who have EGFR-positive tumors, as confirmed by immunohistochemistry (IHC) and/or fluorescence in-situ hybridization (FISH), and have completed up to four cycles of standard adjuvant platinum-based chemotherapy or are chemotherapy naive. They will be randomized 2:1 to receive either Tarceva 150 mg or placebo once daily for two years.

For information on study enrollment, patients or health professionals can call 1-800-572-1932, extension 7821.

About Tarceva

Tarceva is a small molecule designed to target the human epidermal growth factor receptor 1 (HER1) pathway, one of the factors critical to cell growth in NSCLC and other solid tumors. HER1, also known as EGFR, is a component of the HER signaling pathway, which plays a role in the formation and growth of numerous cancers. Tarceva is designed to inhibit the tyrosine kinase activity of the HER1 signaling pathway inside the cell, which may block tumor cell growth. Tarceva is the only HER1/EGFR-targeted therapy proven to significantly prolong survival in second-line NSCLC as a single agent. Tarceva was approved by the FDA in November 2004 for the treatment of patients with locally advanced or metastatic NSCLC after failure of at least one chemotherapy regimen, and in November 2005 for use in combination with gemcitabine chemotherapy for the first-line treatment of locally advanced, unresectable, or metastatic pancreatic cancer.

Results from two earlier large, randomized, placebo-controlled Phase III clinical trials in first-line advanced NSCLC patients showed no clinical benefit with concurrent administration of Tarceva with doublet platinum-based chemotherapy (carboplatin and paclitaxel or gemcitabine and cisplatin) and its use is not recommended in that setting.

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

Tarceva Safety Profile

The safety profile of Tarceva is well established. In the pivotal Phase III study in NSCLC, BR.21, the most common adverse reactions in patients receiving Tarceva were rash and diarrhea. Grade 3/4 rash and diarrhea occurred in 9 and 6 percent of Tarceva-treated patients, respectively. Rash and diarrhea each resulted in discontinuation of 1 percent of Tarceva-treated patients. Dose reduction for rash and diarrhea was needed for 6 and 1 percent of patients, respectively. Historically, there have been infrequent reports of serious interstitial lung disease (ILD), including fatalities, in patients receiving Tarceva for

treatment of NSCLC or other advanced solid tumors. In the pivotal trial in NSCLC, severe pulmonary reactions, including potential cases of interstitial lung disease, were infrequent (0.8 percent) and were equally distributed between treatment arms. The overall incidence of ILD in Tarceva-treated patients from all studies was approximately 0.7 percent.

In the pivotal Phase III study in pancreatic cancer, Trial PA3, the most common adverse events reported were fatigue, rash, nausea, anorexia and diarrhea. Rash was reported in 69 percent of patients who received Tarceva plus gemcitabine and in 30 percent of patients who received gemcitabine plus placebo. Diarrhea was reported in 48 percent of patients who received Tarceva plus gemcitabine and in 36 percent of patients who received gemcitabine plus placebo. Two percent of the patients discontinued Tarceva because of rash and 2 percent because of diarrhea. In addition, severe and potential fatal adverse events included interstitial lung disease-like complications, myocardial infarction or ischemia, cerebrovascular accident, and microangiopathic hemolytic anemia with thrombocytopenia.

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, eye diseases and diabetes. (OSI) Oncology is focused on developing molecular targeted therapies designed to change the paradigm of cancer care. (OSI) Eyetech specializes in the development and commercialization of novel therapeutics to treat diseases of the eye. (OSI) Prosidion is 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. Macugen® (pegaptanib sodium injection) is approved in the United States and Europe for the treatment of neovascular age-related macular degeneration. OSI commercializes Macugen in partnership with Pfizer Inc. 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 and other foreign review processes 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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