OSI Pharmaceuticals Announces That Roche Has Received Negative CHMP Opinion in European Union on Tarceva(R) in Pancreatic Cancer

MELVILLE, N.Y.--(BUSINESS WIRE)--July 28, 2006--OSI Pharmaceuticals, Inc. (Nasdaq: OSIP) announced today that Roche, its international partner for Tarceva® (erlotinib), received a negative opinion from the European Committee for Medicinal Products for Human Use (CHMP), regarding approval of Tarceva in combination with gemcitabine chemotherapy as first-line, once-daily, oral therapy for locally advanced, inoperable or metastatic pancreatic cancer. Roche is evaluating its options - including a possible request for re-examination of the decision.

Pancreatic cancer, the tenth most frequently occurring cancer in Europe, has extremely limited treatment options. In the past nine years, the Tarceva-gemcitabine combination has been the only treatment regimen to have shown, in a Phase III clinical trial, a statistically significant improvement in overall survival when administered as initial therapy to patients suffering with advanced pancreatic cancer. In November 2005, the U.S. Food and Drug Administration (FDA) approved the use of Tarceva in combination with gemcitabine chemotherapy for the treatment of locally advanced unresectable or metastatic pancreatic cancer in patients who have not received previous chemotherapy. In addition, Tarceva is currently approved in the U.S. and the European Union, as well as approximately 50 countries worldwide, as a monotherapy for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after failure of at least one prior chemotherapy regimen.

"Pancreatic cancer is known to be an aggressive disease that has one of the highest one-year mortality rates of any cancer," said Gabriel Leung, President, (OSI) Oncology. "It is critically important that new treatment options be made available to patients around the globe. Like our partner, Roche, we are disappointed in the CHMP opinion, but we are confident in the clinical profile and benefits of the Tarceva-gemcitabine combination therapy. We will provide Roche with any support they need as they evaluate their options for next steps."

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.

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 BR.21 NSCLC trial, 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) 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.

CONTACT: OSI Pharmaceuticals
Kathy Galante (Investors/Media)
Wendy Mensch (Media)
631-962-2000
or
Burns McClellan, Inc. (representing OSI)
Kathy Nugent (Media)
205-401-0260
or
Laura Siino (Investors)
212-213-0006

SOURCE: OSI Pharmaceuticals, Inc.