(osi) pharmaceuticals

OSI Pharmaceuticals Announces European Regulatory Approval of Tarceva(R) for Treatment of Patients with Pancreatic Cancer

MELVILLE, N.Y.--(BUSINESS WIRE)--Jan. 29, 2007--OSI Pharmaceuticals, Inc. (Nasdaq: OSIP) and Roche, its international partner for Tarceva® (erlotinib), announced today that the European Commission has granted marketing authorization for Tarceva in combination with gemcitabine as first-line therapy for metastatic pancreatic cancer. The Tarceva-gemcitabine combination is the only new treatment regimen in a decade to show, in a Phase III clinical trial, a statistically significant improvement in overall survival compared with gemcitabine alone, when administered as initial therapy to patients with advanced stages of pancreatic cancer.

"We are pleased that Tarceva will be available to pancreatic cancer patients throughout the European Union," said Gabriel Leung, President, (OSI) Oncology. "Advanced pancreatic cancer is very difficult to treat and it is an important advance that Tarceva, when combined with gemcitabine, has been shown to produce a statistically significant increase in survival in a cancer where the average life expectancy for a newly diagnosed patient is only about four months. We hope that patients facing pancreatic cancer, and the healthcare providers who treat them, will benefit from this new treatment option."

In November 2005, the U.S. Food and Drug Administration (FDA) approved the use of Tarceva in combination with gemcitabine for the first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer in patients who have not received previous chemotherapy. The approval was based on a pivotal study, which demonstrated a 23% improvement in overall survival with gemcitabine plus Tarceva versus gemcitabine alone. This indication for Tarceva is also approved in 15 other countries worldwide.

About Pancreatic Cancer

Pancreatic cancer affects more than 216,000 people worldwide, according to the World Health Organization. In the US, pancreatic cancer accounts for just two percent of new cancer cases each year, but is the fifth leading cause of cancer death. The main risk factors for the disease include advanced age, cigarette smoking, a high-fat diet, diabetes mellitus, chronic inflammation of the pancreas (pancreatitis) - especially hereditary pancreatitis, and a family history of pancreatic cancer. The symptoms vary depending upon the location of the tumor in the pancreas, but include weight loss, abdominal pain and jaundice.

Additional Tarceva Information

Tarceva was approved by the FDA in November 2004 for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after failure of at least one chemotherapy regimen. 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 non-small cell lung cancer (NSCLC) and other solid tumors. HER1, also known as EGFR, is a component of the HER signalling 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.

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 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 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 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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SOURCE: OSI Pharmaceuticals, Inc.