(osi) pharmaceuticals

OSI Pharmaceuticals Announces Acceptance of a Tarceva(R) Supplemental New Drug Application in Pancreatic Cancer for Review by the U.S. Food and Drug Administration; Tarceva's sNDA is Granted Priority Review Designation by the FDA

MELVILLE, N.Y.--(BUSINESS WIRE)--July 6, 2005--OSI Pharmaceuticals, Inc. (NASDAQ: OSIP) announced today that the U.S. Food and Drug Administration (FDA) has accepted for filing and review the supplemental New Drug Application (sNDA) for use of Tarceva® (erlotinib) plus gemcitabine chemotherapy for the treatment of advanced pancreatic cancer in patients who have not received previous treatment. Tarceva is the only EGFR therapy shown to provide a statistically significant survival benefit in patients treated in first-line locally advanced or metastatic pancreatic cancer in combination with gemcitabine. In addition, Tarceva has been granted priority review classification by the FDA. Based on this priority review status, the FDA has six months from receipt of the sNDA data, or until November 2, 2005, to take action on the sNDA filing.

"We look forward to continuing to work closely with the FDA through this review process in hopes of bringing a new therapeutic treatment option to pancreatic cancer patients," stated Colin Goddard, Ph.D., Chief Executive Officer of OSI Pharmaceuticals.

The acceptance of the sNDA filing satisfies provisions for a $7 million milestone payment by Genentech, Inc. to OSI. The milestone will be accounted in accordance with EITF 00-21 and therefore the revenues will be recognized over the life of the product. As such the milestone is not expected to materially impact 2005 earnings.

About Pancreatic Cancer

The American Cancer Society predicts that in 2005 about 32,180 people in the United States will be diagnosed with pancreatic cancer and about 31,800 will die of the disease. Although pancreatic cancer accounts for 2 percent of new cancer cases in the United States, it is the fourth leading cause of all cancer deaths.

About Tarceva

Tarceva is a small molecule designed to target the human epidermal growth factor receptor 1 (HER1) pathway, which is 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 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 and is an oral tablet indicated for daily administration for the treatment of patients with locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen. Results from two earlier large, randomized, placebo-controlled 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

In the pivotal 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 NSCLC studies was approximately 0.7 percent.

About OSI Pharmaceuticals

OSI Pharmaceuticals is committed to "shaping medicines and changing lives" by discovering, developing and commercializing high-quality and novel pharmaceutical products that extend life or improve the quality of life for cancer and diabetes patients worldwide. The company operates through two business teams, (OSI) Oncology and (OSI) Prosidion. (OSI) Oncology is

focused on developing molecular targeted therapies designed to change the paradigm of cancer care. (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. OSI markets Tarceva through partnerships with Genentech, Inc. in the U.S. and with Roche throughout the rest of the world. For additional information about OSI, please visit http://www.osip.com.

In addition to Tarceva, (OSI) Oncology exclusively markets Novantrone® (mitoxantrone concentrate for injection) for its approved oncology indications and markets Gelclair® Bioadherent Oral Gel for the relief of pain associated with oral mucositis. The research and development pipeline consists of novel molecularly targeted anti-cancer agents focused on signal transduction pathways involved in cell proliferation, apoptosis and angiogenesis. The most advanced of these programs, targeting the co-inhibition of c-kit and VEGFR, has two candidates in development.

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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