(osi) pharmaceuticals

OSI Pharmaceuticals Announces that Tarceva-R- Receives Positive Opinion in EU for the Treatment of Patients with Advanced Lung Cancer

MELVILLE, N.Y.--(BUSINESS WIRE)--June 27, 2005--OSI Pharmaceuticals, Inc. (NASDAQ:OSIP) announced today that its ex-U.S. partner for Tarceva® (erlotinib), Roche, received a positive opinion from the European Committee for Medicinal Products for Human Use (CHMP) recommending approval of Tarceva 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. Tarceva is an oral tablet indicated for daily administration and was approved in the U.S. for NSCLC in November 2004. Following the CHMP recommendation, an approval decision for Tarceva by the European Commission is anticipated within 90 days.

"The CHMP recommendation is an important milestone toward making Tarceva available for lung cancer patients throughout the European Union," stated Colin Goddard, Ph.D., Chief Executive Officer of OSI Pharmaceuticals. "We congratulate our colleagues at Roche on their progress and continue to project the launch of Tarceva in the EU during the final quarter of 2005."

"This decision is proof of the impressive survival benefit that Tarceva offers patients with late stage lung cancer," said William M Burns, CEO Division Roche Pharmaceuticals. "This brings new hope to lung cancer patients who have currently very limited treatment options."

The CHMP has recommended that Tarceva is indicated for the treatment of patients with locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen. When prescribing Tarceva, factors associated with prolonged survival should be taken into account. No survival benefit or other clinically relevant effects of the treatment have been demonstrated in patients with EGFR-negative tumors.

The CHMP recommendation is based on data from a pivotal Phase III study, Trial BR.21, which compared Tarceva to placebo for the treatment of patients with advanced NSCLC, following failure of first or second-line chemotherapy. As in the U.S. label, no mandatory testing for EGFR is required in the CHMP recommendation.

About NSCLC

Lung cancer is the most common cancer worldwide with 1.2 million new cases annually with someone, somewhere dying of the disease every 30 seconds. NSCLC accounts for almost 80 percent of all lung cancer cases and there are few treatment options available. There are an estimated 370,000 people suffering with lung cancer each year in Europe.

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 U.S. Food and Drug Administration 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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