(osi) pharmaceuticals

OSI Pharmaceuticals Announces Tarceva(R) Granted Approval in the European Union for the Treatment of Advanced Non-Small Cell Lung Cancer

MELVILLE, N.Y.--(BUSINESS WIRE)--Sept. 21, 2005--OSI Pharmaceuticals, Inc. (NASDAQ:OSIP) announced today that its international partner for Tarceva® (erlotinib), Roche, received approval from the European Commission 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 is approved in the United States, Canada, and Switzerland. Tarceva is the only epidermal growth factor receptor (EGFR) therapy to demonstrate in a Phase III trial an increase in survival for advanced NSCLC patients.

"We are pleased that lung cancer patients in the European Union now have a new treatment option with a proven survival benefit, coupled with a manageable side effect profile," said Colin Goddard, Ph.D., Chief Executive Officer of OSI Pharmaceuticals. "We congratulate our partner, Roche, on their efforts, and continue to work closely with both Roche and Genentech to explore additional uses of Tarceva in solid tumors and in combination with other therapies."

The European Commission approved Tarceva 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 lung cancer patients with EGFR-negative tumors.

The EU approval is based on data from a pivotal Phase III study, Trial BR.21, which was recently published in The New England Journal of Medicine. The study compared Tarceva to placebo for the treatment of patients with advanced NSCLC, following failure of first or second-line chemotherapy. As with the U.S., Swiss, and Canadian approvals, no mandatory testing for EGFR is required.

"Despite being the biggest cancer killer, lung cancer is an often neglected disease," said Dr. Giuseppe Giaccone, VU Medical Center, Amsterdam. "Over 50 percent of lung cancer patients in Europe are not receiving second-line treatment. With the approval of Tarceva, physicians now have a viable alternative to chemotherapy for their patients."

About Non-Small Cell Lung Cancer

According to the World Health Organization, 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 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.

In May 2004, OSI filed for a supplemental New Drug Application to the US Food and Drug Administration for the use of Tarceva plus gemcitabine chemotherapy in the treatment of patients with advanced pancreatic cancer who have not received any previous treatment. Tarceva is the first drug to significantly improve survival in a Phase III trial when added to gemcitabine chemotherapy in first-line pancreatic cancer compared to gemcitabine alone. Additional early-stage trials of Tarceva are being conducted in other solid tumors.

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 three/four rash and diarrhea occurred in nine and six percent of Tarceva-treated patients, respectively. Rash and diarrhea each resulted in discontinuation of one percent of Tarceva-treated patients. Dose reduction for rash and diarrhea was needed for six and one 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.

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.

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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