(osi) pharmaceuticals

OSI Pharmaceuticals Announces Tarceva Granted Approval in Canada for the Treatment of Advanced Non-Small Cell Lung Cancer

MELVILLE, N.Y.--(BUSINESS WIRE)--July 13, 2005--OSI Pharmaceuticals, Inc. (Nasdaq:OSIP) announced today that Health Canada has approved Tarceva® (erlotinib) for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC), following failure of first or second-line chemotherapy. Tarceva is approved in the United States and in Switzerland and had 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 advanced NSCLC. An approval decision by the European Commission is anticipated over the next several months. Tarceva is an oral tablet indicated for daily administration.

"We congratulate our colleagues at Roche on this approval," stated Colin Goddard, Ph.D., Chief Executive Officer of OSI Pharmaceuticals. "We are pleased that Tarceva is being made available to lung cancer patients throughout the world and that with the broad-based survival benefit demonstrated by Tarceva, coupled with its side effect profile, patients and doctors have available a treatment option other than traditional chemotherapy. With our partners, Genentech and Roche, our commitment to further expand the label and use of Tarceva includes adjuvant and first-line treatment of lung cancer in patients with other tumor types and in combination with other targeted therapies."

The Canadian approval indicates Tarceva 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, and whose EGFR expression status is positive or unknown.

As in the U.S. and Swiss labels, no mandatory testing for EGFR is required. The Canadian approval 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.

The pivotal study included 731 patients with advanced NSCLC for whom one or more chemotherapy regimens had failed. Tarceva demonstrated a survival benefit in essentially all subsets of patients examined including males and females, patients of Asian and non-Asian origins, patients with adenocarcinoma and squamous cell histology, patients with good as well as impaired performance status and both smokers and non-smokers. Median and one-year survival of the overall population in the BR.21 study was improved by 42.5 percent (6.7 versus 4.7 months) and 45 percent (31.2 versus 21.5 percent), respectively, and patients were treated with Tarceva for an average of just over four months in the study (23% of patients were on therapy for more than 6 months). Certain subsets of patients, including never smokers and patients who had tumors determined to be EGFR positive, were seen to have a large survival benefit in response to treatment with Tarceva. The sub-group of patients who never smoked had a substantial survival benefit with a hazard ratio of 0.42 (hazard ratio is a measure of the risk of death and a hazard ratio of <1 indicates a survival benefit). The sub-group of smokers also had a survival benefit (hazard ratio = 0.87) despite the fact that this group was also seen to have a 24 percent higher rate of Tarceva clearance (higher clearance rates lead to lower levels of exposure to drug).

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 ILD, 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.

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 NSCLC

According to the World Health Organization, there are more than 1.2 million cases worldwide of lung and bronchial cancer each year, causing approximately 1.1 million deaths annually. It is estimated that more than 173,000 people will be diagnosed with lung cancer in the United States in 2005. According to the National Cancer Institute, lung cancer is the single largest cause of cancer deaths in the United States and is responsible for nearly 30 percent of cancer deaths in this country. NSCLC is the most common form of the disease and accounts for almost 80 percent of all lung cancers.

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.

For Tarceva full prescribing information, please call 1-877-TARCEVA or visit http://www.tarceva.com.

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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