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OSI Pharmaceuticals Announces Tarceva Granted First European Approval in Switzerland; First and Only Agent Approved in its Class to Show a Survival Benefit

MELVILLE, N.Y.--(BUSINESS WIRE)--March 22, 2005--OSI Pharmaceuticals, Inc. (NASDAQ: OSIP) announced today that the Swiss health authority, Swissmedic, has approved Tarceva™ (erlotinib) 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. Tarceva is the only drug in the epidermal growth factor receptor (EGFR) class to demonstrate in a Phase III clinical trial an increase in survival in advanced NSCLC patients.

"Tarceva offers new hope to people who are suffering from this lung cancer," said William M. Burns, CEO of Roche's Pharmaceuticals Division. "Tarceva is the first medicine in its class with a proven survival and without some of the unpleasant side effects of chemotherapy."

"We would like to congratulate our colleagues at Roche on the first European approval of Tarceva," stated Colin Goddard, Ph.D., Chief Executive Officer of OSI Pharmaceuticals. "We are pleased with the launch of Tarceva in the U.S. to date and we continue to believe that Tarceva will emerge as a fundamentally important new agent in changing the paradigm for the treatment of cancer patients around the world. With our partners, Genentech and Roche, we are committed to executing a post-approval development plan, studying Tarceva in earlier stage lung cancer patients, in patients with other tumor types and combinations with other targeted therapies."

As with the U.S. label, Tarceva is indicated for all NSCLC patients after failure of at least one prior chemotherapy regimen and contains no restrictions on its use regarding EGFR status, mutation status, gender, smoking history, histology or ethnicity. OSI was responsible for the U.S. filing of Tarceva in advanced NSCLC which received U.S. FDA approval in November 2004. In addition, a Marketing Authorization Application was submitted by Roche to the European Health Authorities in August 2004.

The Swiss health authority's decision to approve Tarceva was based on the pivotal BR.21 study in 731 patients with advanced NSCLC. 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 (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 less than 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 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. Six and one percent of patients needed dose reduction for rash and diarrhea, 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 Phase III trial, 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 0.6 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 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. 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. A Phase III clinical trial of Tarceva has been completed in pancreatic cancer, and 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 is currently being

evaluated in an extensive clinical program by a global alliance among OSI Pharmaceuticals, Genentech and Roche.

About Lung Cancer

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 2004. 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 OSI Pharmaceuticals

OSI Pharmaceuticals is a leading biotechnology company primarily focused on the discovery, development and commercialization of high-quality pharmaceutical products that extend life or improve the quality of life for cancer and diabetes patients worldwide. OSI's primary business remains oncology, but the Company has a second business interest in the area of diabetes through its Prosidion subsidiary based in the United Kingdom. Tarceva™, OSI's flagship product, is the first OSI drug discovered and developed by OSI to obtain FDA approval and the only EGFR inhibitor to have demonstrated the ability to improve survival in non-small cell lung cancer and pancreatic cancer. OSI exclusively markets Novantrone® (mitoxantrone concentrate for injection) for the approved oncology indications and markets Gelclair® for the relief of pain associated with oral mucositis. For additional information about the company, please visit http://www.osip.com.

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