

## **OSI Pharmaceuticals Announces Submission of New Drug Application for Tarceva(R) in Japan**

MELVILLE, N.Y.--(BUSINESS WIRE)--April 17, 2006--OSI Pharmaceuticals, Inc. (Nasdaq: OSIP) announced today that a New Drug Application has been submitted in Japan covering the use of its flagship product, Tarceva® (erlotinib), for the treatment of advanced or recurrent non-small cell lung cancer (NSCLC). The application was submitted to the Japanese Ministry of Health, Labour and Welfare (MHLW) by Chugai Pharmaceutical, Co., Ltd., a Japanese affiliate to Roche, OSI's international partner for Tarceva. Tarceva is currently approved in the United States, the European Union, and approximately 50 countries worldwide for the treatment of patients with locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen.

"We applaud our colleagues at Chugai and Roche for their commitment to bringing this important treatment option to lung cancer patients in Japan as quickly as possible," said Gabriel Leung, President, OSI Oncology. "We expect Japan to be among the top countries in terms of sales potential for Tarceva, and to be a key growth driver for this product."

The filing is based on results of a Phase II study that confirmed the safety and efficacy of Tarceva for Japanese patients, along with the data from the NSCLC study BR.21, which compared Tarceva to placebo for the treatment of patients with advanced NSCLC after failure of at least one prior chemotherapy regimen.

### About Lung Cancer

According to the World Health Organization, lung cancer is the most common cancer worldwide, with 1.2 million new cases annually. NSCLC accounts for almost 80 percent of all lung cancer cases. In Japan specifically, the estimated incidence of lung cancer was about 85,000 cases in 2005.

### About Tarceva

Tarceva is a small molecule designed to target the human epidermal growth factor receptor 1 (HER1) pathway, 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. 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 (FDA) in November 2004.

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.

In November 2005, the FDA approved Tarceva in combination with gemcitabine chemotherapy for the treatment of advanced pancreatic cancer in patients who have not received previous chemotherapy. Tarceva is the first drug in a Phase III trial to have shown a significant improvement in overall survival when added to gemcitabine chemotherapy as initial treatment for pancreatic cancer. Tarceva is the only EGFR therapy proven to significantly prolong survival in first-line locally advanced or metastatic pancreatic cancer in combination with gemcitabine.

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

### Tarceva Safety Profile

Tarceva has a well-established safety profile. In the BR.21 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 studies was approximately 0.7 percent.

In the Phase III study in pancreatic cancer, the most common adverse events reported were fatigue, rash, nausea, anorexia

and diarrhea. Rash was reported in 69 percent of patients who received Tarceva plus gemcitabine and in 30 percent of patients who received gemcitabine plus placebo. Diarrhea was reported in 48 percent of patients who received Tarceva plus gemcitabine and in 36 percent of patients who received gemcitabine plus placebo. Two percent of the patients discontinued Tarceva because of rash and 2 percent because of diarrhea. In addition, severe and potential fatal adverse events included interstitial lung disease-like complications, myocardial infarction or ischemia, cerebrovascular accident, and microangiopathic hemolytic anemia with thrombocytopenia.

#### 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 patients with cancer, eye diseases and diabetes. The Company operates through three business teams, (OSI) Oncology, (OSI) Eyetech and (OSI) Prosidion. (OSI) Oncology is focused on developing molecular targeted therapies designed to change the paradigm of cancer care. (OSI) Eyetech specializes in the development and commercialization of novel therapeutics to treat diseases of the eye. (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 United States and with Roche throughout the rest of the world. Macugen® (pegaptanib sodium injection) is approved in the United States and Europe for the treatment of neovascular age-related macular degeneration. OSI commercializes Macugen in partnership with Pfizer Inc. For additional information about OSI, please visit <http://www.osip.com>.

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 and other foreign review processes 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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