

OSI Pharmaceuticals Announces Launch Date of Tarceva(R) (erlotinib) in Japan

MELVILLE, N.Y.--(BUSINESS WIRE)--Dec. 14, 2007--OSI Pharmaceuticals, Inc. (Nasdaq: OSIP) announced today that Tarceva® (erlotinib) has been listed on Japan's National Health Insurance (NHI) drug reimbursement price list and will be launched in Japan on December 18, 2007. The Japanese Ministry of Health, Labour and Welfare approved Tarceva on October 19, 2007 for the treatment of patients with nonresectable, recurrent and advanced non-small cell lung cancer (NSCLC) which is aggravated following chemotherapy.

"We are pleased that lung cancer patients in Japan will now have access to Tarceva, which has been proven to offer a survival benefit with a well-described side-effect profile," said Gabriel Leung, President, (OSI) Oncology. "We, along with our collaborators Genentech and Roche, are committed to making Tarceva available to appropriate patients who may benefit from the drug, and to studying additional potential uses of Tarceva, including as a maintenance therapy in first-line NSCLC, in combination with other targeted therapies, and in other tumor types."

Chugai Pharmaceutical, Co., Ltd., Roche's alliance partner in Japan, submitted the filing for the Japanese approval and will launch and market Tarceva in Japan. Tarceva is approved in 83 countries including the United States and the European Union for the treatment of patients with locally advanced or metastatic 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 85,000 cases in 2005.

Additional Tarceva Information

Tarceva was approved by the FDA in November 2004 and in the European Union in September 2005 as monotherapy for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after failure of at least one chemotherapy regimen. Results from two earlier large, randomized, placebo-controlled Phase III 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 U.S. Food and Drug Administration (FDA) approved the use of Tarceva in combination with gemcitabine for the first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer in patients who have not received previous chemotherapy. In January 2007, the European Commission granted marketing authorization for Tarceva in combination with gemcitabine for the treatment of metastatic pancreatic cancer. 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 an initial treatment for pancreatic cancer.

Tarceva Safety Information

There have been infrequent reports of serious Interstitial Lung Disease (ILD)-like events, including fatalities, in patients receiving Tarceva for treatment of NSCLC, pancreatic cancer or other advanced solid tumors. In the pancreatic cancer trial, other serious adverse events associated with Tarceva plus gemcitabine and which may have included fatalities, were myocardial infarction/ischemia, cerebrovascular accident and microangiopathic hemolytic anemia with thrombocytopenia. When receiving Tarceva therapy, women should be advised against becoming pregnant or breastfeeding. Tarceva is pregnancy category D. The most common side effects in patients with NSCLC receiving Tarceva monotherapy 150 mg were rash and diarrhea. The most common side effects in patients with pancreatic cancer receiving the combination of Tarceva 100 mg plus gemcitabine were fatigue, rash, nausea, anorexia and diarrhea.

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.

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 medicine and changing lives" by discovering, developing and commercializing high-quality and novel pharmaceutical products designed to extend life and/or improve the quality of life for patients with cancer and diabetes/obesity. The Company's oncology programs are focused on developing molecular targeted therapies designed to change the paradigm of cancer care. OSI's diabetes/obesity efforts are 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 in certain settings. OSI markets Tarceva through partnerships with Genentech, Inc. in the United States and with Roche throughout the rest of the world. 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 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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