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# OSI Pharmaceuticals Announces Pivotal Phase III Tarceva(R) Study Published in the Journal of Clinical Oncology Showed Survival Improvement in Patients with Pancreatic Cancer

MELVILLE, N.Y.--(BUSINESS WIRE)--April 25, 2007--OSI Pharmaceuticals, Inc. (Nasdaq: OSIP) announced today that results published yesterday in the Journal of Clinical Oncology show that adding Tarceva® (erlotinib) to gemcitabine chemotherapy significantly improves survival when administered as first-line therapy to patients with advanced pancreatic cancer. Data from this study, conducted by the National Cancer Institute of Canada (NCIC), formed the basis of both the U.S. and European approvals for Tarceva in this patient population.

"This study is important because it shows the benefit of a new approach to treat this deadly disease," said Dr. Malcolm Moore, Study Chair and Chief of Medical Oncology and Hematology at Princess Margaret Hospital, University of Toronto. "This is the first study in ten years to demonstrate an improvement in survival in pancreatic cancer, and as a physician I'm delighted to have additional treatment options for my patients."

In November 2005, the U.S. Food and Drug Administration (FDA) approved the use of Tarceva (100 mg) 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. The approval was based on this pivotal Phase III study, which demonstrated a 23% improvement in overall survival with gemcitabine plus Tarceva versus gemcitabine alone. In January 2007, the European Commission granted marketing authorization for Tarceva in combination with gemcitabine for the treatment of metastatic pancreatic cancer. This indication for Tarceva is also approved in 15 other countries worldwide.

About Pancreatic Cancer

Pancreatic cancer affects more than 216,000 people worldwide, according to the World Health Organization. In the U.S., pancreatic cancer accounts for just two percent of new cancer cases each year, but is the fifth leading cause of cancer death. Pancreatic cancer is difficult to treat, as it is often resistant to chemotherapy and radiotherapy, and tends to spread quickly to other parts of the body, leading to its high mortality and short life expectancy.

The main risk factors for the disease include advanced age, cigarette smoking, a high-fat diet, diabetes mellitus, chronic inflammation of the pancreas (pancreatitis) - especially hereditary pancreatitis - and a family history of pancreatic cancer. The symptoms vary depending upon the location of the tumor in the pancreas, but include weight loss, abdominal pain and jaundice.

Additional Tarceva Information

Tarceva (150 mg) was approved by the FDA in November 2004 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.

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 signalling 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, and in pancreatic cancer when added to gemcitabine.

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

Tarceva Safety Profile

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, and which may have included fatalities, were myocardial infarction/ischemia, cerebrovascular accident, and microangiopathic hemolytic anemia with thrombocytopenia. The most common side effects in patients with pancreatic cancer receiving Tarceva (100 mg) plus gemcitabine were fatigue, rash,

nausea, anorexia, and diarrhea. Severe rash (5%) and severe diarrhea (5%) each resulted in dose reductions in 2% of patients, and discontinuation in up to 1% of patients. The most common side effects in patients with NSCLC receiving Tarceva monotherapy (150 mg) were mild to moderate rash (9%) and diarrhea (6%) which resulted in 1% of Tarceva-treated patients discontinuing therapy. When receiving Tarceva therapy, women should be advised against becoming pregnant or breastfeeding.

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 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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