(osi) pharmaceuticals

OSI Pharmaceuticals Announces Issuance of Additional U.S. Patent for Tarceva; Extends Patent Exclusivity

MELVILLE, N.Y., Jun 02, 2005 (BUSINESS WIRE) -- OSI Pharmaceuticals, Inc. (NASDAQ: OSIP) today announced the issuance of U.S. Patent No. 6,900,221 by the United States Patent and Trademark Office. The patent is directed to a crystalline polymorph of Tarceva™ (erlotinib), methods for treating various cancers, and processes for production of the crystalline polymorph. The claims in the patent will extend exclusive protection of Tarceva until 2020.

"The issuance of the polymorph patent extends our current intellectual property protection for Tarceva by approximately five years," stated Colin Goddard, Ph.D., Chief Executive Officer of the Company. "With a strong launch underway and solid data from this year's ASCO meeting supporting the evolution of the brand to earlier-stage lung cancer patients; different disease settings; and use in combination regimens with other targeted therapies we continue to believe that Tarceva has a bright future in treating cancer patients."

In the U.S., Tarceva is also protected by U.S. Patent No. 5,747,498, which was issued in 1998, covering composition of matter, processes for its preparation, methods of treating cancer, and pharmaceutical compositions containing Tarceva. Additional patents for Tarceva are also issued in areas outside the U.S., including Europe and Japan.

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.

Tarceva was approved by the FDA in November 2004 and is an oral tablet indicated for daily administration for the treatment of patients with locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen. 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.

Additional early-stage trials of Tarceva are being conducted in other solid tumors. In April 2005, OSI submitted a supplemental New Drug Application (sNDA) with the FDA for use of Tarceva plus gemcitabine chemotherapy for the treatment of advanced pancreatic cancer in patients who have not received any previous treatment. 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

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 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 NSCLC studies was approximately 0.7 percent.

About OSI Pharmaceuticals

OSI Pharmaceuticals is committed to shaping medicines and changing patients' 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 II 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 the company, 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.

SOURCE: OSI Pharmaceuticals, Inc.

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