

OSI Pharmaceuticals Announces Launch of Tarceva-TM-

MELVILLE, N.Y.--(BUSINESS WIRE)--Nov. 22, 2004--OSI Pharmaceuticals, Inc. (Nasdaq: OSIP) announced today the initiation of the launch of Tarceva™ less than two business days after last Thursday's approval of the drug for the treatment of patients with advanced non-small cell lung cancer (NSCLC) after failure of at least one prior chemotherapy. Tarceva™ is priced to wholesalers at \$2,026 per 30-day supply of the 150mg tablets, and is also available at 100mg and 25mg tablet strengths. Tarceva™ is approved for use as a monotherapy in second- and third-line settings and is both the first EGFR inhibitor and the first non-cytotoxic agent to improve survival in advanced NSCLC patients and to be approved in the second-line setting.

"We are pleased to be able to make Tarceva available to lung cancer patients so soon after approval," stated Colin Goddard, Ph.D., Chief Executive Officer of OSI Pharmaceuticals. "We believe that the broad-based nature of the survival benefit demonstrated by Tarceva coupled with its side effect profile will make this a valuable and viable treatment option for lung cancer patients and their doctors. We also have a strong post-approval development plan seeking to expand the label and use of Tarceva to earlier stages of lung cancer patients; to other forms of cancer where EGFR is implicated and where we have seen indications of activity; and to combinations of all targeted therapies which we believe represents a true paradigm shift in the treatment of human cancer. With this plan we are confident that Tarceva can be grown into a major product in the treatment of a variety of cancers."

The Tarceva™ approval was based on the pivotal BR.21 study in 731 patients with advanced NSCLC. The Tarceva package insert includes a summary of the Tarceva™ data as previously presented at the American Society of Clinical Oncology 40th annual meeting in New Orleans, La. in May 2004. Tarceva™ demonstrated a survival benefit in essentially all subsets of patients examined including males and females, 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).

The analysis of tumor samples of EGFR expression was conducted on approximately one-third of the patients in the study for whom tumor samples were available. Patients whose tumors were EGFR positive exhibited a relatively large survival benefit (hazard ratio = 0.65). Although patients whose tumors were EGFR negative did not appear to derive a survival benefit, this group was small and the statistical confidence levels were wide. In this group 3.2 percent of the patients did exhibit a tumor response, one measure of anti-tumor activity. In common with treatment practice the majority of the patients entering the study did not have tumor samples available to determine EGFR status and the survival benefit in this group of patients with unknown EGFR status was robust (a hazard ratio of 0.76). There is no validated test for EGFR in NSCLC and tumor testing is not required prior to the initiation of therapy with Tarceva™.

In the pivotal study, the principal side effects associated with Tarceva™ use are a rash (in 75 percent of patients, with approximately 9 percent of patients exhibiting grade 3/4 rash) and a generally mild-moderate diarrhea (in 54 percent of patients, with approximately 6 percent of patients exhibiting grade 3/4 diarrhea). Infrequent reports of serious interstitial lung disease (ILD) have been observed for patients receiving Tarceva™ and other EGFR inhibitors. However, for Tarceva™, there was no difference in the incidence of ILD in the Tarceva™ and placebo arms in the BR.21 study (0.8 percent incidence rate in both the Tarceva™ and placebo arms). 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>.

About OSI Pharmaceuticals

OSI Pharmaceuticals is a leading biotechnology company primarily focused on the discovery, development, and commercialization of high-quality, next-generation oncology products that both extend life and improve the quality of life for cancer patients worldwide. OSI has a balanced pipeline of oncology drug candidates that includes both novel mechanism-based, gene-targeted therapies focused in the areas of signal transduction, apoptosis, and a next-generation cytotoxic chemotherapy agent. Tarceva™, OSI's flagship product, is the first OSI drug discovered and developed by OSI to obtain FDA approval. OSI exclusively markets Novantrone® (mitoxantrone concentrate for injection) for the approved oncology indications and Gelclair® for the relief of pain associated with oral mucositis. OSI also established Prosidion Limited, an independently operated diabetes and obesity subsidiary based in the United Kingdom. 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.

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SOURCE: OSI Pharmaceuticals, Inc.