OSI Pharmaceuticals Initiates Phase II Study of Tarceva In Non-Small Cell Lung Cancer Patients with Poor Performance Status

MELVILLE, N.Y.--(BUSINESS WIRE)--March 19, 2004--OSI Pharmaceuticals, Inc. (NASDAQ: OSIP) today announced that it has initiated a Phase II randomized study of monotherapy Tarceva™ (erlotinib HCl) versus standard chemotherapy of previously untreated non-small cell lung cancer (NSCLC) patients with a poor performance status. Tarceva™, OSI's leading drug candidate, is designed to block tumor cell growth by inhibiting the tyrosine kinase activity of the HER1/EGFR receptor, thereby blocking the HER1/EGFR signaling pathway inside the cell. Tarceva™ is being developed in a global alliance among OSI, Genentech and Roche.

"Advanced NSCLC patients with a designated poor performance status generally have a low tolerance to standard first-line combination chemotherapy," stated Nicole Onetto, MD, Executive Vice President and Chief Medical Officer at OSI Pharmaceuticals. "This study is designed to evaluate monotherapy Tarceva™ as a therapeutic option to standard chemotherapy treatment for this high-risk sub-population of NSCLC patients."

This multi-center, open-label, randomized study is scheduled to enroll up to 102 patients. The study is designed to evaluate in parallel the efficacy and safety of Tarceva™ monotherapy and of a standard chemotherapy combination (paclitaxel and carboplatin) in poor performance status patients with previously untreated NSCLC. The primary endpoint of this trial is progression-free survival and secondary endpoints include disease-related symptom benefit, tumor response and overall survival. Tarceva™ will be administered at 150mg/day.

In this trial a patient's performance status is measured by the Eastern Cooperative Oncology Group (ECOG) Performance Scale. The Scale ranks the global function of cancer patients according to their level of activity and symptoms from PS0 to PS4 with PS0 patients being fully ambulatory and asymtomatic. To be eligible for this trial, patients need to have moderately impaired performance status graded as 2 (PS2). A PS2 rating is defined as capable of self-care but unable to carry out any work activities; up and about more than 50 percent of waking hours.

About Tarceva™

Tarceva™ is a small molecule designed to target the human epidermal growth factor receptor 1 (HER1) pathway, which is critical to cell growth in many cancers. HER1, also known as EGFR, is a key component of the HER signaling pathway, which often is involved 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 blocks tumor cell growth.

About Non-Small Cell Lung Cancer

According to the World Health Organization, there are more than 1.2 million cases worldwide of lung and bronchial cancer each year, causing approximately 1.1 million deaths annually. According to the National Cancer Institute, lung cancer is the single largest cause of cancer deaths in the United States and is responsible for nearly 30 percent of cancer deaths in the country. NSCLC is the most common form of lung cancer and accounts for almost 80 percent of all cases. At the time of diagnosis, approximately 40% of patients with inoperable NSCLC present with PS2.

About OSI Pharmaceuticals

OSI Pharmaceuticals is a leading biotechnology company 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 and apoptosis and next-generation cytotoxic chemotherapy agents. OSI's most advanced drug candidate, Tarceva™, a small-molecule inhibitor of the HER1 gene, is currently in Phase III clinical trials for lung and pancreatic cancers. OSI has a commercial presence in the U.S. oncology market where it exclusively markets Novantrone® (mitoxantrone concentrate for injection) for approved oncology indications and Gelclair® for the relief of pain associated with oral mucositis.

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 successful marketing of products, product pricing and third-party reimbursement, 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, and other factors described in OSI Pharmaceuticals' filings with the Securities and Exchange Commission. Tarceva™ is an investigational compound and has not yet been determined safe or efficacious in humans for its ultimate intended use.

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