

OSI Pharmaceuticals Announces Acceptance of Tarceva New Drug Application for Review by the U.S. Food and Drug Administration

Tarceva(TM) is Granted Priority Review Designation by the FDA

MELVILLE, N.Y.--(BUSINESS WIRE)--Sept. 30, 2004--OSI Pharmaceuticals, Inc. (NASDAQ:OSIP) announced today that the U.S. Food and Drug Administration (FDA) has accepted for filing and review the New Drug Application (NDA) for the use of Tarceva™ (erlotinib HCl) as a monotherapy for the treatment of patients with advanced non-small cell lung cancer (NSCLC) for whom chemotherapy has failed. The acceptance of the NDA, as well as Roche's earlier filing of a European Marketing Application submitted in August to the European Health Authorities for Tarceva™, satisfies milestone provisions for payments totaling \$10 million by Genentech and Roche to OSI. Additional milestone payments will be paid by Genentech and Roche to OSI upon registration of Tarceva™ in the U.S. and the European Union, respectively, and upon successful filing and registration of Tarceva™ in Japan. Further milestones are also due upon the successful filing and approval of Tarceva™ in a second oncology indication and upon the approval of the first two adjuvant oncology indications in the U.S., Europe and Japan.

OSI also announced that Tarceva™ has been granted priority review classification by the FDA. Based on this priority review status, the FDA has six months from the NDA receipt date, or until January 30, 2005, to take action on the NDA filing.

The Tarceva NDA was previously granted Pilot 1 Status under the FDA's Pilot 1 Program for Continuous Marketing Applications, a new program designed for investigational products that have been given Fast Track status, such as Tarceva™, and that have demonstrated significant promise in clinical trials as a therapeutic advance over available therapy for a disease or condition. Under the Pilot 1 status, the FDA is committed to reviewing each unit of the NDA within six months of each unit submission. The NDA filing for Tarceva™ is based on a pivotal Phase III trial known as BR.21. OSI completed the NDA submission in July 2004.

The BR.21 trial was a double-blind, placebo-controlled study which included 731 patients with advanced NSCLC who had previously received one or two prior chemotherapy regimens. Tarceva™ demonstrated a 42 percent improvement in median survival and improved one-year survival by 45 percent. The trial also demonstrated statistically significant improvement in all secondary endpoints of the trial including time to symptom deterioration, progression-free survival and response rate. The study results make Tarceva™ the first and only targeted therapy to demonstrate an improvement in survival for NSCLC patients. Detailed results of the trial were presented in June at the 40th Annual American Society of Clinical Oncology (ASCO) meeting in New Orleans. The global study was conducted by the National Cancer Institute of Canada Clinical Trials Group based at Queen's University in collaboration with OSI Pharmaceuticals.

Safety

In line with previous clinical studies, adverse events that occurred more often with patients treated with Tarceva™ in the pivotal trial included rash and diarrhea, which were generally mild to moderate in severity. Seventy-five percent of patients receiving Tarceva™ exhibited rash (versus 17 percent in the placebo group) and 54 percent of patients receiving Tarceva™ experienced diarrhea (versus 18 percent for placebo). Dose reductions occurred for rash and diarrhea only in the Tarceva™ arm, six percent and one percent, respectively. In the pivotal study, severe pulmonary events, including potential cases of interstitial lung events, were infrequent and were equally distributed between treatment arms.

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 many cancers. HER1, also known as EGFR, is a key 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. Clinical trials of Tarceva™ are being conducted in other solid tumors, such as pancreatic, ovarian, colorectal, head and neck, kidney, brain and gastrointestinal cancers. Tarceva™ is currently being evaluated in an extensive clinical development program by a global alliance of OSI Pharmaceuticals, Genentech, and Roche.

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 cases.

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 a next-generation cytotoxic chemotherapy agent. OSI's most advanced drug candidate, Tarceva™, a small-molecule inhibitor of the HER1 gene, has successfully completed Phase III clinical trials in lung and pancreatic cancers and is the subject of an ongoing New Drug Application (NDA) in lung cancer. 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. OSI has 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. Tarceva™ is an investigational compound and has not yet been approved as safe or efficacious in humans for its ultimate intended use.

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