OSI Pharmaceuticals Announces Roche Filing of Tarceva -TM- Marketing Application with European Health Authorities

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EU Filing Follows OSI's Earlier Submission of New Drug Application To FDA for Approval of Tarceva™

OSI Pharmaceuticals, Inc. (NASDAQ: OSIP) announced today that its international partner, Roche, submitted a Marketing Authorization Application to the European Health Authorities for Tarceva™ (erlotinib HCl) as a monotherapy for the treatment of patients with advanced non-small cell lung cancer (NSCLC) for whom chemotherapy has failed. Tarceva™ is currently being evaluated in an extensive clinical development program by a global alliance among OSI, Genentech, and Roche.

This European Union (EU) filing, as well as the previously completed submission of a New Drug Application (NDA) to the US Food and Drug Administration for approval of Tarceva™, are based on a pivotal Phase III trial known as BR.21. OSI announced its completion of the NDA submission on August 2, 2004. The NDA had been 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.

"The timely submission of both the US and EU applications underscore the alliance's commitment to bringing Tarceva™ to lung cancer patients around the world as quickly as possible," stated Colin Goddard, Ph.D., Chief Executive Officer of OSI Pharmaceuticals. "We congratulate our colleagues at Roche for their fine efforts and dedication in achieving this milestone."

The BR.21 trial was a double-blind, placebo-controlled study which included 731 patients and compared Tarceva™ to placebo in the treatment of patients with relapsed NSCLC who had previously received chemotherapy. 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, LA. 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, 10 percent and four 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.

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 for lung cancer and is the subject of an ongoing New Drug Application (NDA). 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, 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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