

OSI Pharmaceuticals Announces That Tarceva Has Been Accepted into The FDA's Pilot 1 Program

MELVILLE, N.Y.--(BUSINESS WIRE)--June 29, 2004--OSI Pharmaceuticals, Inc. (NASDAQ:OSIP) announced today that the New Drug Application (NDA) for Tarceva™ (erlotinib HCl), has been accepted onto the U.S. Food and Drug Administration's Pilot 1 Program for Continuous Marketing Applications. The Pilot 1 Program is designed for products that have been designated Fast Track status and have demonstrated significant promise in clinical trials as a therapeutic advance over available therapy for the disease or condition.

"We are pleased that Tarceva™ has been accepted as one of the first drugs to be reviewed under the new Pilot Program," stated Colin Goddard, Ph.D., Chief Executive Officer at OSI Pharmaceuticals. "We are committed to working closely with the FDA to help demonstrate that this innovative program can help companies work together with the FDA to ensure a timely review of agents like Tarceva™ that represent a meaningful step forward in the treatment of diseases for which there is an unmet medical need."

As one of the Prescription Drug User Fee Act (PDUFA) goals, the Pilot 1 Program is designed to expedite the Continuous Marketing Application (otherwise known as "Rolling NDAs") Concept. Under the program, applicants with products meeting the requirements are eligible to submit a limited number of portions (or "Reviewable Units") of their NDA in advance of the complete application. The FDA has agreed to complete reviews of the individual Reviewable Units as they are submitted and to provide early feedback to the applicant. OSI had previously been granted Fast Track status for the advanced NSCLC indication in September 2002 and submitted the non-clinical and CMC sections of the NDA under the standard "rolling submission" provision on January 20, 2004. With the Pilot 1 Program designation the FDA is committed to initiating the review of these sections on a six month review timeline as of the notification of Pilot 1 status. OSI also announced that it has filed the BR.21 study report with the FDA which follows on from the filing of the first clinical section on May 12, 2004. OSI expects to complete its NDA filing for Tarceva over the summer and, assuming a priority review the action date will be six months from the completion of the NDA submission.

About Tarceva™

Tarceva™ 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 currently being evaluated in an extensive clinical development program together with the Company's alliance partners at Genentech and Roche.

Tarceva™ had met all its pre-determined study endpoints (including survival; progression free-survival; time to symptom deterioration; and objective tumor response) in a 731-patient, double blinded, placebo controlled Phase III trial which compared Tarceva™ to placebo in the treatment of patients with advanced or metastatic NSCLC following the failure of first or second line chemotherapy. The study was conducted by the National Cancer Institute of Canada Clinical Trials Group based at Queen's University in collaboration with OSI Pharmaceuticals.

About Fast-Track Status

Under the FDA Modernization Act of 1997, Fast Track designation is limited to a new drug that is intended for the treatment of a serious and life-threatening condition for which there is an unmet medical need. Fast Track status is designed to facilitate the review process by allowing the sponsor to submit sections of an NDA as they become available. Although the FDA has no obligation to begin reviewing sections of the NDA until the final sections of the complete NDA are submitted, the FDA can begin the review of the submitted sections, if resources permit and this can be advantageous to the overall assessment timelines. The Pilot 1 Program extends the Fast Track provisions for a limited number of Fast Track products that have shown significant promise in clinical studies, by committing the FDA to initiating the review early.

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 the 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 next-generation cytotoxic chemotherapy agents. 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 subject to an ongoing rolling submission of an 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 Ltd., 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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