

OSI Pharmaceuticals and Genentech Announce Completion of New Drug Application for FDA Approval of Tarceva

MELVILLE, N.Y. & SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Aug. 2, 2004-- First and Only EGFR Inhibitor to Show Increased Survival in Advanced Non-Small Cell Lung Cancer OSI Pharmaceuticals, Inc. (NASDAQ: OSIP) and Genentech, Inc. (NYSE: DNA) announced today that OSI completed the submission of a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) 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.

"This submission completes the Tarceva™ NDA filing and is a major milestone in our commitment to providing relapsed lung cancer patients with this potential new treatment option as quickly as possible," stated Colin Goddard, Ph.D., Chief Executive Officer of OSI Pharmaceuticals. "We are proud of the efforts of our internal clinical and regulatory teams in completing our first NDA in a timely manner and we appreciate the support of the Genentech team in this process. We will continue to work closely with the FDA as it reviews the Tarceva™ application."

"The improvement in survival observed in the Tarceva™ pivotal trial represents an important medical advance in the treatment of non-small cell lung cancer," said Hal Barron, M.D., Genentech's senior vice president, development and chief medical officer. "Of note, Tarceva™ showed improvement in survival across a broad spectrum of patients in the pivotal study and we believe, if approved, it will provide an important potential treatment option."

The NDA has 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 NDA filing is based on a pivotal Phase III double-blind, placebo-controlled trial that included 731 patients and that compared Tarceva™ to placebo in the treatment of patients with relapsed non-small cell lung cancer who had previously received chemotherapy. Tarceva™ demonstrated a 42 percent improvement in median survival and improved one-year survival by 45 percent. The study 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 non-small cell lung cancer 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 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 by a global alliance among 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 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>.

About Genentech

Genentech is committed to changing the way cancer is treated by establishing a broad oncology portfolio of innovative, targeted therapies with the goal of improving patients' lives. The company is the leading provider of anti-tumor therapeutics in the United States. Genentech is leading clinical development programs for Rituxan® (Rituximab), Herceptin® (Trastuzumab), and Avastin™ (bevacizumab) and markets all three products in the United States either alone (Avastin, which it recently launched in the United States, and Herceptin) or with Biogen Idec Inc. (Rituxan). Genentech has licensed Rituxan, Herceptin and Avastin to Roche for sale by the Roche Group outside of the United States.

The company has a robust pipeline of potential oncology therapies with a focus on four key areas: angiogenesis, apoptosis (i.e. programmed cell death), the HER pathway and B-cell biology. Potential oncology therapies directed at the HER pathway include Tarceva™ (erlotinib) and a therapeutic antibody currently in Phase II trials. Also in early development are a small molecule directed at the hedgehog pathway, a therapy targeting apoptosis and a humanized anti-CD20 antibody for hematology/oncology indications.

Genentech is a leading biotechnology company that discovers, develops, manufactures and commercializes biotherapeutics for significant unmet medical needs. Eighteen of the currently approved biotechnology products originated from or are based on Genentech science. Genentech manufactures and commercializes 12 biotechnology products in the United States. The company has headquarters in South San Francisco, California and is traded on the New York Stock Exchange under the symbol DNA. For additional information about the company and complete prescribing information for marketed products, please visit <http://www.gene.com>.

Regarding OSI

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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SOURCE: OSI Pharmaceuticals, Inc. & Genentech, Inc.