

OSI Pharmaceuticals and Genentech Announce Filing of a Supplemental New Drug Application to the FDA for Tarceva -TM- in Pancreatic Cancer

MELVILLE, N.Y. & SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May 2, 2005--OSI Pharmaceuticals, Inc. (NASDAQ: OSIP) and Genentech, Inc. (NYSE: DNA) announced today that OSI submitted a supplemental New Drug Application (sNDA) with the U.S. Food and Drug Administration (FDA) for use of Tarceva™ (erlotinib) plus gemcitabine chemotherapy for the treatment of advanced pancreatic cancer in patients who have not received any previous treatment. Tarceva is the first drug to significantly improve survival in a Phase III trial when added to gemcitabine chemotherapy in first-line pancreatic cancer compared to gemcitabine alone.

"There is an urgent need for additional therapeutic options for patients with advanced pancreatic cancer and we look forward to working closely with the FDA through this review process," stated Colin Goddard, Ph.D., Chief Executive Officer of OSI Pharmaceuticals.

"Pancreatic cancer is difficult to treat and is a disease in which only 20 percent of patients survive one year after diagnosis. The improved survival observed in the Phase III trial that is the basis for this filing represents a potential treatment advance for both patients and physicians," said Hal Barron, M.D., Genentech's senior vice president of Development and chief medical officer. "We would like to recognize our colleagues at OSI Pharmaceuticals for their hard work on this important filing."

The sNDA filing is based on a pivotal Phase III multi-center, randomized, double-blind, placebo-controlled trial evaluating Tarceva in patients with locally advanced or metastatic pancreatic cancer. Results of the trial were presented in January at the Second Annual Gastrointestinal Cancers Symposium in Hollywood, Fla. A total of 569 patients were randomized in the study, to receive Tarceva plus gemcitabine or gemcitabine plus placebo.

The study demonstrated a statistically significant 23.5 percent improvement in overall survival for patients receiving Tarceva plus gemcitabine compared to patients receiving gemcitabine plus placebo. Twenty-four percent of patients receiving Tarceva plus gemcitabine were alive after one year compared to 17 percent of patients receiving gemcitabine plus placebo. Median survival in the Tarceva plus gemcitabine arm was 6.4 months compared to 5.9 months in the gemcitabine plus placebo arm. An exploratory analysis of survival by pre-treatment characteristics also showed that patients with metastatic disease and patients with poor performance status derived a significant survival benefit. Progression-free survival in the Tarceva plus gemcitabine arm also was significantly improved, although there was virtually no difference in tumor response (9 percent in patients receiving Tarceva plus gemcitabine versus 8 percent in the gemcitabine plus placebo arm).

The analysis of safety data did not reveal any unexpected safety signals beyond that seen in previous studies of Tarceva in both monotherapy and combination settings. As expected, rash and diarrhea were the principal Tarceva related side effects seen in the study. Rash was reported by 72 percent of patients who received Tarceva plus gemcitabine and by 28 percent of patients who received gemcitabine plus placebo. Diarrhea was reported by 51 percent of patients who received Tarceva plus gemcitabine and by 36 percent of patients who received gemcitabine plus placebo. Possible interstitial lung disease (ILD) was experienced by 2.1 percent of patients in the Tarceva plus gemcitabine arm compared with 0.4 percent in the gemcitabine plus placebo arm. These ILD incidence levels for the combination of Tarceva and gemcitabine were higher than the 0.8 percent incidence reported for both monotherapy Tarceva and placebo in the pivotal BR.21 study in advanced NSCLC. However, the incidence of possible ILD from all clinical studies with Tarceva is 0.7 percent.

About Pancreatic Cancer

According to the World Health Organization, more than 216,000 people worldwide are diagnosed each year with pancreatic cancer. The American Cancer Society estimates that in 2005 approximately 32,180 people in the United States will be diagnosed with pancreatic cancer and approximately 31,800 will die of the disease. Most pancreatic tumors originate in the exocrine duct cells or in the cells that produce digestive enzymes (acinar cells). Called adenocarcinomas, these tumors account for nearly 95 percent of pancreatic cancers.

About Tarceva

Tarceva is currently approved by the FDA as a monotherapy for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of at least one prior chemotherapy regimen and is an oral tablet indicated for daily administration. Results from two earlier large, randomized, placebo-controlled clinical trials in first-line advanced NSCLC patients showed no clinical benefit with concurrent administration of Tarceva with doublet platinum-based chemotherapy (carboplatin and paclitaxel or gemcitabine and cisplatin) and its use is not recommended in that setting.

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 a number of different cancer types. HER1, also known as EGFR, is a 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. Tarceva is the only EGFR therapy to show in a Phase III trial improved survival for advanced NSCLC patients. Additional early-stage trials of Tarceva are being conducted in other solid tumors. For Tarceva full prescribing information, please call 1-877-TARCEVA or visit <http://www.tarceva.com>.

About Tarceva Safety

In the pivotal NSCLC trial, the most common adverse reactions in patients receiving Tarceva were rash and diarrhea. Severe grade 3/4 rash and diarrhea occurred in nine and six percent of Tarceva-treated patients, respectively. Rash and diarrhea each resulted in discontinuation of one percent of Tarceva-treated patients. Dose reduction was needed for six and one percent of patients for rash and diarrhea, respectively. Historically, there have been infrequent reports of serious interstitial lung disease (ILD), including fatalities, in patients receiving Tarceva for treatment of NSCLC or other advanced solid tumors. In the Phase III trial, severe pulmonary reactions, including potential cases of interstitial lung disease, were infrequent (0.8 percent) and were equally distributed between treatment arms. The overall incidence of possible ILD in Tarceva-treated patients from all studies was approximately 0.7 percent.

About OSI Pharmaceuticals

OSI Pharmaceuticals is a leading biotechnology company primarily focused on the discovery, development and commercialization of high-quality pharmaceutical products that extend life or improve the quality of life for cancer and diabetes patients worldwide. OSI's primary business remains oncology, but the Company has a second business interest in the area of diabetes through its subsidiary, Prosidion Limited, based in the United Kingdom. Tarceva™ (erlotinib), OSI's flagship product, is the first drug discovered and developed by OSI to obtain FDA approval and the only EGFR inhibitor to have demonstrated the ability to improve survival in non-small cell lung cancer and pancreatic cancer. OSI exclusively markets Novantrone® (mitoxantrone concentrate for injection) for the approved oncology indications and markets Gelclair® Bioadherent Oral Gel for the relief of pain associated with oral mucositis. For additional information about the company, please visit <http://www.osip.com>.

About Genentech BioOncology

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), Avastin™ (bevacizumab), and Tarceva™ (erlotinib), and markets all four products in the United States, either alone (Avastin and Herceptin) or with Biogen Idec Inc. (Rituxan) or OSI Pharmaceuticals, Inc. (Tarceva). Genentech has licensed Rituxan, Herceptin, and Avastin, and OSI Pharmaceuticals has licensed Tarceva 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. A therapeutic antibody directed at the HER pathway is currently in Phase II trials and 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. A considerable number of the currently approved biotechnology products originated from, or are based on, Genentech science. Genentech manufactures and commercializes multiple biotechnology products directly in the United States, and receives royalties or other income from companies that are licensed to market its products outside of 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, 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, the ability to effectively market products, and other factors described in OSI Pharmaceuticals' filings with the Securities and Exchange Commission.

For full prescribing information, including Boxed Warnings for Avastin, Rituxan and Herceptin, or for Tarceva full prescribing information, please call 800-821-8590 or visit www.gene.com

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