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Genentech and OSI Pharmaceuticals Initiate Phase IIIB Clinical Trial of Tarceva in Advanced Non-Small Cell Lung Cancer

SOUTH SAN FRANCISCO, Calif. and MELVILLE, N.Y., Sept. 10/PRNewswire-FirstCall/ -- Genentech, Inc. (NYSE: DNA and OSI Pharmaceuticals,Inc. (Nasdaq: OSIP) announced today the initiation of a Phase IIIB clinical study of the investigational therapy Tarceva™ (erlotinib HCl) in patients with second- and third-line non-small cell lung cancer (NSCLC) who have previously received chemotherapy. The clinical trial, called the ACT (Access to Care, Tarceva) trial, is a multi-center, open-label study of once-daily oral Tarceva, with endpoints of survival and response rate.

The study will enroll a patient population consistent with the pivotal Tarceva trial, which is the basis for the New Drug Application (NDA) that was filed with the U.S. Food and Drug Administration (FDA) earlier this year. Patient enrollment for the trial has begun and will end when the FDA issues an approval decision regarding whether Tarceva is safe and effective as a monotherapy for the treatment of patients with advanced NSCLC after failure of at least one prior chemotherapy regimen. Patients interested in learning about the ACT trial can call 888-662-6728.

About Tarceva

Tarceva is an investigational product designed to block tumor cell growth by inhibiting the tyrosine kinase activity of the epidermal growth factor receptor (HER1/EGFR), 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 of Genentech, OSI Pharmaceuticals and Roche.

In July 2004, OSI filed an NDA for Tarceva with the FDA as a monotherapy for patients with advanced NSCLC after failure of at least one standard chemotherapy regimen. The FDA designated Tarceva Pilot 1 status under its Pilot 1 Program for Continuous Marketing Applications, a new program designed for investigational products that have been granted 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. Tarceva is the first and only targeted therapy to demonstrate an improvement in survival for advanced NSCLC patients.

The NDA filing is based on a pivotal Phase III double-blind, placebo-controlled trial, which included 731 patients and that compared Tarceva to placebo in the treatment of patients with advanced NSCLC after failure of at least one prior chemotherapy regime. Detailed results of the trial were presented in June at the 40th Annual American Society of Clinical Oncology (ASCO) meeting in New Orleans.

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 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 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), 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 HCl) 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. 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 licenses several additional products to other companies. The company has headquarters in South San Francisco, California and is traded on the New York Stock Exchange under the symbol DNA. For press releases and additional information about the company, please visit http://www.gene.com .

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 .

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