Phase III Study of Tarceva in Combination With Chemotherapy Improves Survival in Pancreatic Cancer Patients

- Data Presented at Plenary Session at Annual ASCO Meeting -

ORLANDO, Fla., May 14, 2005 /PRNewswire-FirstCall via COMTEX/ -- Genentech, Inc. (NYSE: DNA) and OSI Pharmaceuticals (Nasdaq: OSIP) today presented additional data from a randomized Phase III clinical trial of Tarceva™ (erlotinib) in advanced pancreatic cancer. 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. These data were presented today at the 41st Annual Meeting of the American Society of Clinical Oncology (ASCO).

“These ongoing trials reinforce our belief in the potential application of Tarceva in a variety of cancers,” said Gabe Leung, president of (OSI) Oncology at OSI Pharmaceuticals. “Based on these data OSI recently submitted to the FDA a supplemental New Drug Application for Tarceva in pancreatic cancer and will be working closely with the FDA through the review process.”

“The improvement in survival demonstrated by Tarceva in second- and third-line non-small cell lung cancer as monotherapy and in first-line pancreatic cancer in combination with gemcitabine, underscores our commitment to explore the use of Tarceva in multiple cancers, with the hope of bringing new treatment options to patients,” said Hal Barron, M.D., Genentech's senior vice president, development and chief medical officer.

Tarceva plus gemcitabine compared to gemcitabine alone in patients with advanced pancreatic cancer. A Phase III trial of the National Cancer Institute of Canada Clinical Trial Group (NCIC-CTG) (Abstract #1 - Saturday, May 14, 2005 4:00 p.m. EDT)

A Phase III randomized study of Tarceva in combination with gemcitabine met its primary endpoint by demonstrating a statistically significant 23.5 percent improvement in overall survival (or a hazard ratio of 0.81, which can also be referred to as a 19 percent reduction in the risk of death), the study's primary efficacy endpoint, when compared to patients receiving gemcitabine plus placebo. The data were presented by Malcolm Moore, M.D., of Princess Margaret Hospital in Toronto, Ontario.

The international study was a multi-center, double-blind, placebo-controlled Phase III trial evaluating Tarceva in patients with locally advanced or metastatic pancreatic cancer. The study randomized 569 patients to receive either gemcitabine plus concurrent Tarceva or gemcitabine plus placebo.

In addition to the improvement in overall survival, 24 percent of patients receiving Tarceva plus gemcitabine were alive after one year compared to 17 percent of patients receiving gemcitabine plus placebo, a 41 percent increase in one-year survival. Median survival in the Tarceva plus gemcitabine arm was 6.4 months compared to 5.9 months in the gemcitabine plus placebo arm. Progression-free survival in the Tarceva plus gemcitabine arm was also significantly improved by 32 percent (or a hazard ratio of 0.76, which can also be referred to as a 24 percent reduction in the risk of progression). 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.)

There were no significant differences in overall survival for patients whose tumors were shown to be EGFR-positive (hazard ratio = 0.74, n = 86) versus those whose tumors were shown to be EGFR-negative (hazard ratio = 0.82, n = 76).

The analysis of safety data did not reveal any unexpected safety signals beyond those seen in previous studies of Tarceva in both monotherapy and combination settings. An increase in mild-to-moderate (i.e. Grade 1 and 2) adverse events including rash, diarrhea and hematological toxicity were seen in the Tarceva plus gemcitabine arm. Rash was reported for 72 percent of patients who received Tarceva plus gemcitabine and for 29 percent of patients who received gemcitabine plus placebo. Diarrhea was reported by 56 percent of patients who received Tarceva plus gemcitabine and by 41 percent of patients who received gemcitabine plus placebo. Grade 3/4 rash in the Tarceva plus gemcitabine arm was 6 percent compared to 1 percent in the gemcitabine plus placebo arm. Other Grade 3/4 adverse events were similar in both arms, and rates for the events in the Tarceva plus gemcitabine arm were infection (17 percent), fatigue (15 percent), diarrhea (6 percent), dehydration (3 percent) and pneumonitis (2 percent).

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 non-small cell lung cancer (NSCLC) and other solid tumors. 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 HER1/EGFR-targeted therapy proven to significantly prolong survival in second-line NSCLC as a single agent.

Tarceva was approved by the FDA in November 2004 and is an oral tablet indicated for daily administration for the treatment of patients with locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen. 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.

Additional early-stage trials of Tarceva are being conducted in other solid tumors. In April 2005, OSI submitted a supplemental New Drug Application (sNDA) with the FDA for use of Tarceva plus gemcitabine chemotherapy for the treatment of advanced pancreatic cancer in patients who have not received any previous treatment. For Tarceva full prescribing information, please call 1-877-TARCEVA or visit http://www.tarceva.com.

Tarceva Safety Profile

In the pivotal NSCLC trial, the most common adverse reactions in patients receiving Tarceva were rash and diarrhea. Grade 3/4 rash and diarrhea occurred in 9 and 6 percent of Tarceva-treated patients, respectively. Rash and diarrhea each resulted in discontinuation of 1 percent of Tarceva-treated patients. Dose reduction for rash and diarrhea was needed for 6 and 1 percent of patients, 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 pivotal trial in NSCLC, 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 ILD in Tarceva-treated patients from all studies was approximately 0.7 percent.

About Pancreatic Cancer

The American Cancer Society predicts that in 2005 about 32,180 people in the United States will be diagnosed with pancreatic cancer and about 31,800 will die of the disease. Although pancreatic cancer accounts for 2 percent of new cancer cases in the United States, it is the fourth leading cause of all cancer deaths.

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 alone (Avastin and Herceptin), with Biogen Idec Inc. (Rituxan) or with OSI Pharmaceuticals (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. Potential oncology therapies directed at the HER pathway include a therapeutic antibody currently in Phase II trials. Also in early development are a small molecule directed at the hedgehog pathway, a soluble human protein 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, Calif., 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.

About OSI Pharmaceuticals

OSI Pharmaceuticals is committed to shaping medicines and changing patients' lives by discovering, developing and commercializing high-quality and novel pharmaceutical products that extend life or improve the quality of life for cancer and diabetes patients worldwide. The company operates through two business teams, (OSI) Oncology and (OSI) Prosidion. (OSI) Oncology is focused on developing molecular targeted therapies designed to change the paradigm of cancer care. (OSI) Prosidion is committed to the generation of novel, targeted therapies for the treatment of type II diabetes and obesity. OSI's
flagship product, Tarceva™ (erlotinib), 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 both non-small cell lung cancer and pancreatic cancer patients. OSI markets Tarceva™ through partnerships with Genentech Inc. in the U.S. and with Roche throughout the rest of the world. For additional information about the company, please visit http://www.osip.com.

In addition to Tarceva, (OSI) Oncology exclusively markets Novantrone® (mitoxantrone concentrate for injection) for its approved oncology indications and markets Gelclair® Bioadherent Oral Gel for the relief of pain associated with oral mucositis. The research and development pipeline consists of novel molecularly targeted anti-cancer agents focused on signal transduction pathways involved in cell proliferation, apoptosis and angiogenesis. The most advanced of these programs, targeting the co-inhibition of c-kit and VEGFR, has two candidates in development.

Roche in Oncology

The Roche Group, including its members Genentech in the United States and Chugai in Japan, is the world's leading provider of cancer care products, including anti-cancer treatments, supportive care products and diagnostics. Its oncology business includes an unprecedented five products proven to provide survival benefit in different major tumour indications: Avastin, Herceptin, and Xeloda in advanced-stage breast cancer, Herceptin in early-stage HER2-positive breast cancer, MabThera in non-Hodgkin's lymphoma, Avastin and Xeloda in colorectal cancer, Avastin and Tarceva in non-small cell lung cancer and Tarceva in pancreatic cancer.

In addition to these anti-cancer agents, the Roche oncology portfolio includes a comprehensive collection of medicines that can help improve the quality of life of cancer patients: Bondronat (for prevention of skeletal events in patients with breast cancer and bone metastases, hypercalcaemia of malignancy), Kytril (for chemotherapy and radiotherapy-induced nausea and vomiting), Neupogen (for cancer-related neutropenia), and NeoRecormon (for anaemia in various cancer settings). CERA is the most recent demonstration of Roche's commitment to anaemia management. Other oncology products include Furtulon (for colorectal cancer) and Roferon-A (for hairy cell and chronic myeloid leukaemia, Kaposi's sarcoma, malignant melanoma, renal cell carcinoma). The Roche Group's cancer medicines generated sales of more than 7.7 billion Swiss francs in 2004.

In addition to the medicines, Roche is developing new diagnostic tests that will have a significant impact on disease management for cancer patients in the future. With a broad portfolio of tumour markers for prostate, colorectal, liver, ovarian, breast, stomach, pancreas and lung cancer, as well as a range of molecular oncology tests, Roche will continue to be the leader in providing cancer-focused treatments and diagnostics.

The unmatched Roche oncology portfolio as well as an extensive external innovation base through collaborations with companies and academia is what makes it possible for Roche to provide more effective cancer therapies.

In the United States, Herceptin, MabThera (Rituxan), Avastin and Tarceva are marketed either by Genentech alone or together with its partners Biogen Idec Inc. (MabThera) and OSI (Tarceva). Outside of the United States, Roche and its Japanese partner Chugai are responsible for the marketing of these medicines.

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 http://www.gene.com.

SOURCE Genentech, Inc.; OSI Pharmaceuticals