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Data from Phase III Study Show Tarceva Plus Gemcitabine Significantly Improves Survival Compared to Gemcitabine Alone in Advanced Pancreatic Cancer Patients

Tarceva is the Only Epidermal Growth Factor Receptor (EGFR) Therapy to Show an Improvement in Survival in Pancreatic Cancer

HOLLYWOOD, Fla.--(BUSINESS WIRE)--Jan. 27, 2005--OSI Pharmaceuticals, Inc. (Nasdaq: OSIP), Genentech, Inc. (NYSE: DNA), and Roche (SWX Zurich) announced today that a randomized Phase III clinical study of Tarceva™ (erlotinib) plus gemcitabine chemotherapy in patients with locally advanced or metastatic pancreatic cancer met its primary endpoint by demonstrating a statistically significant 23.5 percent improvement in overall survival when compared to patients receiving gemcitabine plus placebo. The data were presented at the Second Annual Gastrointestinal Cancers Symposium in Hollywood, Fla. Tarceva is the first drug shown in a Phase III trial to prolong survival when added to the standard of care (gemcitabine) in the treatment of patients with previously untreated advanced pancreatic cancer.

Results from the Pancreatic Cancer Study

The study data demonstrated an improvement in overall survival for patients receiving Tarceva plus gemcitabine compared to patients receiving gemcitabine plus placebo (hazard ratio = 0.81, p-value = 0.025; a hazard ratio of less than one indicates a decreased risk of death and a p-value of less than 0.05 indicates statistical significance). 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 survival benefit. Progression-free survival in the Tarceva plus gemcitabine arm also was significantly improved (hazard ratio = 0.76, p-value = 0.003), 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 international study was a multi-center, randomized, double-blind, placebo-controlled Phase III trial evaluating Tarceva at 100 mg/day or 150 mg/day in patients with locally advanced or metastatic pancreatic cancer. The study randomized patients to receive either gemcitabine plus concurrent Tarceva or gemcitabine plus placebo. Gemcitabine was dosed at 1,000 mg/m2 IV once weekly. A total of 569 patients were randomized in the study, 521 patients were randomized to receive 100 mg/day of Tarceva plus gemcitabine or gemcitabine plus placebo, and 48 patients received 150 mg/day of Tarceva plus gemcitabine or gemcitabine plus placebo. Approximately 75 percent of the patients in the study had metastatic disease and 25 percent had locally advanced disease. The study had sites in the United States, Asia, Canada, Europe, Australia and South America. The study was conducted by the National Cancer Institute of Canada Clinical Trials Group based at Queen's University, Ontario in collaboration with OSI Pharmaceuticals.

A preliminary analysis of the 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.

"The results of this trial underscore the importance and potential utility of Tarceva in combination with gemcitabine in the treatment of patients with pancreatic cancer," stated Malcolm Moore, M.D., Study Chair and Medical Oncologist at Princess Margaret Hospital in Toronto, Canada and Chair of the Gastrointestinal Disease Site, NCIC Clinical Trials Group. "These Tarceva results represent an important medical advance in the treatment of patients with pancreatic cancer and we hope will open the door to a completely new approach to treating the disease."

"The positive outcome of this trial is great news for pancreatic patients and their families. OSI is working closely with the FDA to complete a Supplemental New Drug Application (sNDA) which we hope to file in the first half of 2005," stated Colin Goddard, Ph.D., Chief Executive Officer of OSI Pharmaceuticals. "Tarceva has now shown a survival benefit in two cancers that are widely recognized among the most difficult to treat, pancreatic cancer and lung cancer."

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.

"Historically, few therapies have been proven to significantly extend survival in patients diagnosed with pancreatic cancer. We hope the encouraging data announced today will provide promising therapies for pancreatic cancer patients in the future," said Julie Fleshman, president and CEO, PanCAN (Pancreatic Cancer Action Network).

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). 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 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. Tarceva is the only EGFR inhibitor to have demonstrated a survival benefit in NSCLC. 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. 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. Grade three/four 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. Six and one percent of patients needed dose reduction 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 ILD in Tarceva-treated patients from all studies was approximately 0.6 percent.

About OSI Pharmaceuticals

OSI Pharmaceuticals is a leading biotechnology company primarily focused on the discovery, development, and commercialization of high-quality 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 signal transduction inhibitors, apoptosis inducers, and a next-generation cytotoxic chemotherapy agent. Tarceva, OSI's flagship product, is the first OSI drug discovered and developed by OSI to obtain FDA approval. OSI exclusively markets Novantrone® (mitoxantrone concentrate for injection) for the approved oncology indications and markets Gelclair® for the relief of pain associated with oral mucositis. OSI also established Prosidion Limited, a diabetes and obesity subsidiary based in the United Kingdom. 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.

Roche in Oncology

Within the last five years the Roche Group including its partners Genentech in the US and Chugai in Japan has become the world's leading provider of anti-cancer treatments, supportive care products and diagnostics. Its oncology business includes an unprecedented four marketed products with survival benefit in different major tumour indications: Xeloda and Herceptin in advanced stage breast cancer, MabThera in non-Hodgkin's lymphoma, and Avastin in colorectal carcinoma. In the United States Herceptin, MabThera and Avastin are marketed either by Genentech alone or together with Biogen Idec Inc. Outside of the United States, Roche and its Japanese partner Chugai are responsible for the marketing of these drugs.

The Roche oncology portfolio also includes NeoRecormon (anaemia in various cancer settings), Bondronat (prevention of skeletal events in breast cancer and bone metastases patients, hypercalcaemia of malignancy), Kytril (chemotherapy and radiotherapy-induced nausea and vomiting) and Roferon-A (hairy cell and chronic myeloid leukaemia, Kaposi's sarcoma, malignant melanoma, renal cell carcinoma). CERA is the most recent demonstration of the commitment to anaemia management. The Roche Group's cancer medicines generated sales of more than 3.3 billion Swiss francs in the first half of 2004.

Roche is developing new tests, which 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, we will continue to be the leaders in providing cancer focused treatments and diagnostics.

Roche Oncology has four research sites (two in the US, Germany and Japan) and four Headquarter Development sites (two in the US, UK and Switzerland).

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.

The statements made in this press release relating to the expected timeframe for the sNDA filing and the promise of Tarceva in treating pancreatic cancer are forward looking and actual results could differ materially. Among other things, the filing timeframe could be delayed by unexpected safety or efficacy concerns, additional time requirements for data analysis or sNDA preparation, discussions with the FDA, the need for additional clinical studies, or FDA actions or delays; and the promise of Tarceva in treating pancreatic cancer could be affected by all of the foregoing and the failure to receive FDA approval, competition, pricing, the ability to supply product or a product withdrawal.

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