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Tarceva Extends Survival of Patients with Relapsed Non-Small Cell Lung Cancer

MELVILLE, N.Y. & SOUTH SAN FRANCISCO, Calif. & BASEL, Switzerland--(BUSINESS WIRE)--April 26, 2004--

Only HER1/EGFR-inhibitor to show survival benefit in a randomized, controlled Phase III trial OSI Pharmaceuticals, Inc. (Nasdaq:OSIP), Genentech, Inc. (NYSE:DNA), and Roche (SWX Zurich) today announced that a Phase III study of Tarceva™ (erlotinib HCl), an investigational HER1/EGFR-inhibitor agent in previously treated patients with non-small cell lung cancer (NSCLC), met its primary endpoint of improving overall survival, with patients receiving Tarceva™ living longer than those in the placebo arm of the study. The trial also met secondary endpoints including improving time to symptomatic deterioration, progression-free survival and response rate. OSI will work with the Food and Drug Administration (FDA) to complete the New Drug Application (NDA) for Tarceva™ during the summer.

This international study, which was sponsored by OSI, was conducted by the National Cancer Institute of Canada Clinical Trials Group at Queens University in collaboration with OSI. Results of this Phase III trial will be presented at the upcoming 2004 Annual Meeting of the American Society of Clinical Oncology (ASCO) in New Orleans, Louisiana from June 5 to 8.

"We are extremely pleased with the results of this trial. This is the first controlled Phase III study of a HER1/EGFR-targeted agent which has shown an improvement in survival in any disease setting," said Colin Goddard, Ph.D., Chief Executive Officer of OSI Pharmaceuticals. "Because Tarceva™ was granted Fast Track designation from the FDA, we will work with the agency to make Tarceva™ available as quickly as possible to patients."

"The results of this controlled trial of Tarceva™ represent a significant advancement in treating patients with relapsed non-small cell lung cancer because Tarceva™ was shown to both extend life and provide symptomatic improvement," said Frances A. Shepherd, M.D., FRCPC, Scott Taylor Chair in Lung Cancer Research at the Princess Margaret Hospital, Professor of Medicine at the University of Toronto and principal investigator of the trial.

"Approximately 173,000 Americans will be diagnosed with lung cancer this year," said Hal Barron, M.D., Genentech's senior vice president of Development and chief medical officer. "We are excited that pending FDA approval, patients with relapsed non-small cell lung cancer will have a new treatment alternative that has clinically demonstrated the ability to prolong survival."

About the Study

The multi-center, randomized, controlled Phase III study evaluated Tarceva™ at 150 mg/day in patients with stage IIIB/IV recurrent NSCLC. The study participants must have received at least one, but no more than two prior chemotherapy regimens. The study randomized patients to receive either Tarceva™ or placebo. This was an international study with sites in Canada, Argentina, Australia, Brazil, Chile, Germany, Greece, Hong Kong, Israel, Mexico, New Zealand, Romania, Singapore, South Africa, Sweden, Thailand and the United States.

A preliminary analysis of safety data showed that the toxicities reported were as expected in patients receiving Tarceva™ compared to those receiving placebo. In line with previous clinical studies, events that occurred more often with patients treated with Tarceva™ included mainly mild to moderate diarrhea and rash.

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 many cancers. HER1, also known as EGFR, is a key 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. Results of a Phase III trial of Tarceva™ in pancreatic cancer are expected in the second half of 2004. Early-stage trials of Tarceva™ are being conducted in other solid tumors, such as ovarian, colorectal, head and neck, renal cell carcinoma, glioma and gastrointestinal cancers.

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. It is estimated that more than 173,000 people will be diagnosed with lung cancer in the United States in 2004. 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. Non-small cell

lung cancer is the most common form of the disease and accounts for almost 80 percent of all lung cancer.

About the Companies

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 next-generation cytotoxic chemotherapy agents. 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. For additional information about the company, please visit http://www.osip.com.

Genentech is committed to changing the way cancer is treated by establishing a broad oncology portfolio of innovative, targeted therapies that can improve patients' lives. The company is the leading provider of anti-tumor therapeutics in the United States. Genentech has developed Rituxan ®, Herceptin® and Avastin ™ and markets all three products in the United States either alone (Avastin and Herceptin) or with Biogen-IDEC (Rituxan). Genentech has licensed Rituxan, Herceptin and Avastin to the Roche Group for sale outside of the U.S. The company has a robust pipeline of potential oncology therapies, including the small molecule therapy Tarceva ™, and a therapeutic antibody directed at the HER pathway in Phase II trials. To broaden Genentech's portfolio of targeted cancer therapies, research programs leverage the company's expertise in the HER and angiogenesis pathways, as well as pathways that instruct cancer cells to die (i.e., apoptosis), and B-cell biology.

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 13 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, please visit http://www.gene.com.

Within the last five years the Roche Group 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: Herceptin, MabThera, Xeloda and Avastin which has been launched in the US recently, treat a range of malignancies such as breast cancer, non-Hodgkin's lymphoma and colorectal cancer. Other key products include NeoRecormon (anaemia in various cancer settings), Bondronat (prevention of skeletal events in breast cancer and bone metastases patients, hypercalcemia of malignancy), Kytril (chemotherapy and radiotherapy-induced nausea and vomiting) and Roferon-A (leukaemia, Kaposi's sarcoma, malignant melanoma, renal cell carcinoma). Roche's cancer medicines generated sales of more than 6 billion Swiss francs in 2003.

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).

Conference Call Information

OSI Pharmaceuticals will host a conference call today, Monday, April 26, 2004 at 11:00AM Eastern Time. Dr. Colin Goddard will host the conference call to discuss today's announcement. To access the live call or the seven-day archive via the Internet, log on to www.osip.com. Please connect to the Company's website at least 15 minutes prior to the conference call to ensure adequate time for any software download that may be needed to access the webcast. Alternatively, please call 1-800-915-4836 (US) or 1-973-317-5319 (international) to listen to the call. Telephone replay is available approximately two hours after the call through May 3, 2004. To access the replay, please call 1-800-428-6051 (US) or 1-973-709-2089 (international). The conference ID number is 353362.

Genentech will be offering a live webcast of a discussion by Genentech management of the Tarceva results on Monday, April 26, 2004, at 9:00 a.m. Pacific Time (PT). The live webcast may be accessed on Genentech's website at http://www.gene.com. This webcast will also be available after the call via the website until 5:00 p.m. PT on May 3, 2004. An audio replay of the webcast will be available beginning at 12:00 noon PT on April 26, 2004 through 5:00 p.m. PT on May 3, 2004. Access numbers for this replay are: 1-800-642-1687 (U.S./Canada) and 1-706-645-9291 (international); Conference ID number is 7108002.

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 successful marketing of products, product pricing and third-party

reimbursement, 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 the companies' filings with the Securities and Exchange Commission. Tarceva™ is an investigational compound and has not yet been determined safe or efficacious in humans for its ultimate intended use.

The statements made in this press release relating to the expected timeframes for NDA filing and for data availability from the Phase III trial in pancreatic cancer are forward-looking and actual results could differ materially. Among other things, the timeframes could be affected by safety or efficacy concerns, manufacturing issues, additional time requirements to achieve study endpoints or for data analysis or NDA preparation, discussions with the FDA, the need for additional clinical studies, or FDA actions or delays.

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