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Tarceva U.S. Phase III Non-Small Cell Lung Cancer Clinical Trial Completes Patient Enrollment

SOUTH SAN FRANCISCO, Calif., MELVILLE, N.Y., & BASEL, Switzerland--(BUSINESS WIRE)--Aug. 1, 2002--Genentech (NYSE:DNA), OSI Pharmaceuticals (Nasdaq:OSIP), and Roche announced today that the randomized U.S. Phase III clinical trial evaluating the investigational therapy, Tarceva™ (erlotinib HCl), in combination with standard chemotherapy for patients with chemotherapy-naive stage IIIB/IV non-small cell lung cancer (NSCLC), has completed patient enrollment. Tarceva™ is a small molecule HER1/EGFR inhibitor being developed by Genentech, OSI, and Roche.

Approximately 1,050 patients were enrolled in the nationwide, multi-center trial conducted by Genentech. "This program has received significant investigator and patient interest. A Phase III trial in non-small cell lung cancer, conducted by Roche, currently is enrolling patients outside the U.S. This trial, which continues on-track, also will be included in the alliance's potential regulatory submission in the U.S. for front-line chemotherapy-naive non-small cell lung cancer," said Susan D. Hellmann, M.D., M.P.H., Genentech's executive vice president, Development and Product Operations, and chief medical officer.

Tarceva™ is a small molecule designed to target the human epidermal growth factor receptor (HER1) pathway, also known as EGFR, which is critical to cell growth in many cancers. HER1 is a key component of the HER signaling pathway, which is often involved in the formation and growth of numerous cancers. Tarceva™ is designed to inhibit specifically the tyrosine kinase activity of HER1, thereby blocking the signaling pathway with the intent of potentially inhibiting tumor cell growth.

Tarceva™ is being studied in NSCLC and pancreatic cancer through randomized and controlled Phase III studies with survival as the primary endpoint. Present plans call for the participation of more than 3,000 patients in the currently designed Phase III clinical trial program for Tarceva™. Additionally, the U.S. National Cancer Institute's Cancer Therapy Evaluation Program (CTEP) is conducting numerous Tarceva™ trials in solid tumors, such as ovarian cancer, head and neck cancer, renal cell carcinoma, colorectal, and other gastrointestinal cancers.

Genentech, Inc., is a leading biotechnology company that discovers, develops, manufactures, and commercializes biotherapeutics for significant unmet medical needs. Fifteen of the currently approved biotechnology products originated from, or are based on, Genentech science. Genentech manufactures and commercializes ten biotechnology products directly in the United States. The company has headquarters in South San Francisco, Calif., and is traded on the New York Stock Exchange under the symbol DNA.

OSI Pharmaceuticals is a leading biotechnology company primarily focused on the discovery, development, and commercialization of innovative products for the treatment of cancer. OSI has built a pipeline of discovery programs and drug candidates addressing major, unmet medical needs in cancer and selected opportunities, including diabetes, arising from the company's extensive drug discovery research programs that represent significant commercial opportunities.

Headquartered in Basel, Switzerland, Roche is one of the world's premier research-oriented health care companies in the fields of pharmaceuticals, diagnostics, and vitamins. It is a proven leader in the worldwide oncology arena. Roche is responsible for clinical trials with, and marketing of, Tarceva™ (erlotinib HCl) in all countries outside the United States.

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, uncertainties related to the identification of lead compounds, the successful pre-clinical development thereof, the completion of clinical trials, the FDA review process and other governmental regulation, pharmaceutical collaborators' ability to successfully develop and commercialize drug candidates, competition from other pharmaceutical companies, product pricing and third-party reimbursement, and other factors described on OSI Pharmaceuticals' 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.

SOURCE: OSI Pharmaceuticals

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