

Genentech and OSI Pharmaceuticals Announce FDA Fast-track Designation for Tarceva

SOUTH SAN FRANCISCO, Calif. & MELVILLE, N.Y.--(BW HealthWire)--May 14, 2002--Genentech, Inc. (NYSE:DNA) and OSI Pharmaceuticals, Inc. (Nasdaq:OSIP) today announced that the U.S. Food and Drug Administration (FDA) has designated Tarceva™ (erlotinib HCl, OSI-774) a Fast Track Product for the treatment of chemotherapy-naïve Stage III/IV non-small cell lung cancer patients. Tarceva™ is a small molecule EGFR inhibitor being developed by Genentech, OSI and Roche.

"Lung cancer remains one of the most devastating forms of cancer, with a five-year survival rate of only 3 percent for patients with metastatic disease," said Susan D. Hellmann, M.D., M.P.H., Genentech's executive vice president, Development and Product Operations, and chief medical officer. "Designation of Tarceva™ as a Fast Track Product recognizes the seriousness of the condition and unmet medical need in lung cancer. We are currently enrolling approximately 1,000 chemotherapy-naïve non-small cell lung cancer patients into a randomized Phase III clinical trial evaluating Tarceva™ in combination with chemotherapy with survival as the primary endpoint."

Under the FDA Modernization Act of 1997, the Fast Track Program of the FDA is designed to facilitate the development and expedite the review of a new drug that is intended for the treatment of a serious or a life-threatening condition, and demonstrates the potential, of a drug candidate, to address unmet medical needs for such a condition.

Tarceva™ is a small molecule designed to target the epidermal growth factor receptor (EGFR) pathway, which is critical to cell growth in many cancers. EGFR, also known as 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 EGFR/HER1 thereby blocking the signaling pathway with the intent of potentially inhibiting tumor cell growth.

Tarceva™ is being studied thoroughly in non-small cell lung cancer and in pancreatic cancer through randomized and controlled Phase III studies with survival as the primary endpoint. Additionally, the U.S. National Cancer Institute Cancer Therapy Evaluation Program (CTEP) is planning to conduct numerous Tarceva™ trials in solid tumor types such as ovarian, metastatic colorectal, head and neck, renal cell carcinoma, and pancreatic. It is anticipated that more than 3,000 patients will participate in the currently designed Phase III clinical trial program for Tarceva™.

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 stem 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, California 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.

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™ (erlotinib HCl, OSI-774) is an investigational compound and has not yet been determined safe or efficacious in humans for its ultimate intended use.

Additional information is available at www.osip.com or www.gene.com.

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