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Tarceva -- erlotinib HCl -- Shows Encouraging Safety Profile and Activity in Phase I Clinical Study in Patients with Malignant Glioma

CHICAGO--(BUSINESS WIRE)--May 31, 2003-- Genentech, Inc. (NYSE: DNA) and OSI Pharmaceuticals, Inc. (NASDAQ: OSIP) announced encouraging results from a Phase I clinical study of Tarceva™ (erlotinib HCl) in patients with malignant glioma (brain cancer). Tarceva is designed to inhibit the tyrosine kinase activity of the HER1/EGFR signaling pathway inside the cell, which may block tumor cell growth.

"We are very encouraged by the safety profile and the response rates seen in this Phase I study in glioma, a disease in which HER1/EGFR may play a special role," stated Susan D. Hellmann, M.D., M.P.H., Genentech's executive vice president, Development and Product Operations, and chief medical officer. "Glioma is the most malignant form of brain cancer, and there is a tremendous unmet medical need because current therapies have shown minimal impact to alter the course of the disease."

Based on an encouraging safety profile and clinical activity observed in this Phase I study (Abstract #394), Genentech and OSI have made a decision to move forward with a Phase II trial of Tarceva in glioma in the United States. This Phase II clinical trial will be conducted in collaboration with the Accelerate Brain Cancer Cure (ABC2) Clinical Network of leading neuro-oncology centers. ABC2 is a non-profit foundation that funds novel translational science aimed at the discovery of a cure for brain cancer.

Results of Phase I Glioma Clinical Trial

The study, led by Michael Prados, M.D., of the University of California, San Francisco, evaluated the safety and pharmacokinetics (PK) of Tarceva in patients with malignant glioma. Patients with stable or progressive malignant glioma were treated with Tarceva, starting at 100 mg/day and received an additional 50 mg/day until a dose-limiting toxicity occurred. The 26 patients were stratified based on the use of enzyme inducing antiepileptic drugs (EIAEDs), which are used to prevent seizures. In addition to receiving Tarceva, some patients also received temozolomide, a type of chemotherapy.

Sixteen percent of the evaluable patients (8/49) achieved a response after treatment with Tarceva. Dr. Prados reported that the number of objective responses observed in this study was encouraging. Dose-limiting toxicities occurred in six patients, primarily due to skin rash. To date, the maximum tolerated dose has not been reached.

"In addition to encouraging indications of clinical activity, the dose escalation component of this study has allowed us to use Tarceva at doses where essentially all patients develop rash, which in other studies appears to correlate with improved survival," said Nicole Onetto, M.D., executive vice president and chief medical officer, OSI Pharmaceuticals.

About Brain Cancer

Primary brain cancer kills up to 10,000 Americans a year. Glioma is the most common form of primary brain cancer, afflicting approximately 7,000 patients in the United States each year. Brain tumors are currently treated by surgery, radiation therapy and chemotherapy, either individually or in combination, but the disease remains one of the most significant unmet clinical needs in oncology.

Global Clinical Development Program

The Tarceva™ Phase III program in non-small cell lung cancer (NSCLC) consists of three Phase III randomized studies: an OSI trial is assessing Tarceva as a single agent in a second- third-line setting, and two trials -- one conducted by Genentech and the other by Roche -- are assessing Tarceva as a first-line agent in combination with approved chemotherapy regimens. The study in second- third-line NSCLC is investigating the potential survival benefit of single agent Tarceva at 150 mg/day. This 700-patient study is being conducted by OSI in collaboration with the National Cancer Institute Canada Clinical Trials Group (NCIC CTG) and completed enrollment in January 2003. This is the only single-agent controlled Phase III study of an EGFR-targeted agent designed to detect a survival advantage in second- third-line NSCLC.

In addition, OSI is sponsoring a Phase III trial evaluating Tarceva in patients with previously-untreated advanced pancreatic cancer. The Phase III study is also being conducted in collaboration with the NCIC CTG, and is a randomized, placebo-controlled study assessing the use of Tarceva in combination with gemcitabine, the only approved first-line chemotherapy treatment for pancreatic cancer. Improvement in patient survival is the primary endpoint in this study. Accrual was completed in January 2003, and the trial includes approximately 450 patients.

About Tarceva™

Tarceva™ is a small molecule designed to target the human epidermal growth factor receptor 1 (HER1) pathway, which is critical to cell growth in many cancers. HER1, also known as EGFR, is a key component of the HER signaling pathway, which often is involved 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 blocks tumor cell growth. Tarceva currently is being studied as an oral dosage tablet.

The alliance of Genentech, OSI, and Roche provides all of the essential elements for the rapid, comprehensive, and competitive development of Tarceva, including extensive experience with targeted therapy research, demonstrated comprehensive development, and marketing expertise of next-generation cancer therapies in the United States and globally.

Genentech 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 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 press releases and additional information about the company, please visit http://www.gene.com.

OSI Pharmaceuticals is a leading biotechnology company focused on the discovery, development and commercialization of high-quality, next-generation oncology products that both extend and improve the quality-of-life for cancer patients worldwide. OSI has a balanced pipeline of oncology drug candidates that includes both next-generation cytotoxic agents and novel mechanism-based, gene-targeted therapeutics focused in the areas of signal transduction and apoptosis. OSI's most advanced drug candidate, Tarceva™ (erlotinib HCl), a small-molecule inhibitor of the HER1 gene, is currently in Phase III clinical trials for lung and pancreatic cancers. OSI has a commercial presence in the U.S. oncology market where it exclusively markets Novantrone® (mitoxantrone concentrate for injection) for approved oncology indications.

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, pharmaceutical collaborators' ability to successfully develop and commercialize drug candidates, competition from other pharmaceutical companies, and other factors described in OSI Pharmaceuticals' filings with the Securities and Exchange Commission. Tarceva™ (erlotinib HCl) is an investigational compound and has not yet been determined safe or efficacious in humans for its ultimate intended use.

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