

## **Tarceva -- erlotinib HCl -- Phase II Clinical Trial Initiated in Patients with Malignant Glioma**

### **U.S. Food and Drug Administration Grants Orphan Drug Status**

SOUTH SAN FRANCISCO, Calif. & MELVILLE, N.Y.--(BUSINESS WIRE)--Aug. 8, 2003--Genentech, Inc. (NYSE:DNA - News) and OSI Pharmaceuticals, Inc. (Nasdaq:OSIP - News) announced today that the first patient has been enrolled in a multi-center, open-label, Phase II clinical trial evaluating the safety and efficacy of Tarceva™ (erlotinib HCl), in patients with malignant glioma (brain cancer). Tarceva is designed to block tumor cell growth by inhibiting the tyrosine kinase activity of the HER1/EGFR signaling pathway inside the cell.

"Currently, there are very few treatment options for patients with malignant glioma. Given that HER1/EGFR may play a special role in this disease and the positive results observed in a Phase I study of Tarceva in glioma, we feel it is important to continue studying Tarceva to determine its potential in this difficult-to-treat setting," said Gwen Fyfe, M.D., Genentech's vice president of Clinical Hematology/Oncology. "Beginning a Phase II clinical trial in glioma is another step forward in our comprehensive global clinical development program of Tarceva, which includes Phase III studies in non-small cell lung cancer and pancreatic cancer."

The HER1/EGFR signaling pathway is believed to be important in the growth of malignant glioma tumors where evidence of HER1/EGFR overexpression, gene amplification and expression of the EGFRvIII mutant form of the gene have all been documented.

The new Phase II clinical trial plans to enroll up to 110 patients who have experienced their first relapse of malignant glioma, and is being conducted by Genentech 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. For further information about Tarceva clinical trials, please call 888-662-6728.

### **Orphan Drug Status Granted for Malignant Glioma**

The companies also announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug status for Tarceva in patients with malignant glioma. This is the first HER1/EGFR-inhibitor to receive such classification.

The FDA grants orphan drug status for any drug intended for rare diseases or conditions affecting less than 200,000 persons per year in the United States. This is possible under the Orphan Drug Act of 1983, which encompasses a set of laws that encourage the development of treatments for rare diseases.

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 a significant unmet clinical need 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: 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, and a trial being conducted by OSI in collaboration with the National Cancer Institute Canada Clinical Trials Group (NCIC CTG) is assessing Tarceva as a single agent in a second-/third-line setting.

In addition, OSI is sponsoring a Phase III trial evaluating Tarceva in patients with previously-untreated advanced pancreatic cancer. The Phase III study also is 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.

### **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.

## About Genentech

Genentech is a leading biotechnology company that discovers, develops, manufactures, and commercializes biotherapeutics for significant unmet medical needs. Sixteen of the currently approved biotechnology products originated from or are based on Genentech science. Genentech manufactures and commercializes 11 biotechnology products 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. For additional information about the company, please visit <http://www.gene.com>.

## About OSI

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 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.

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, the Company's and its collaborators' abilities 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™ is an investigational compound and has not yet been determined safe or efficacious in humans for its ultimate intended use.

### Contact:

Genentech, Inc.

Colleen Sweeney, 650-225-7739 (Media)

Kathee Littrell, 650-225-1034 (Investors)

or

OSI

Kathy Galante, 631-962-2000

Source: Genentech