

# Media Release



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## Phase III trials of Tarceva plus chemotherapy in lung cancer patients do not meet primary endpoint

Ongoing programme studying Tarceva in a variety of solid tumor types to continue

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Roche (SWX Zurich), Genentech, Inc. (NYSE:DNA) South San Francisco, USA and OSI Pharmaceuticals, Inc. (Nasdaq:OSIP) Melville, USA, today announced that the primary endpoint of improving overall survival was not met in two first-line randomised controlled Phase III studies of Tarceva (erlotinib) plus standard chemotherapy in advanced non-small cell lung cancer patients. In light of data of comparable studies with a competitive product, the results of this study are not unexpected. The outcome of the two studies does not affect the financial projections communicated earlier by Roche.

"Further work is needed to provide more insight into the role of EGFR inhibitors combined with chemotherapy in this setting," said William M. Burns, Head of Roche Pharmaceuticals. "In order to assess the therapeutic potential of EGFR inhibition, we will continue to analyse the data for potential subsets of patients who are more likely to benefit from treatment with Tarceva in combination with chemotherapy. We will continue our clinical development programme and believe Tarceva may have utility in treating a variety of other cancers."

The two studies are part of an ongoing comprehensive clinical development programme, which includes a Phase III study of Tarceva as a single-agent in a second/third-line setting, a Phase II study of Tarceva as a single-agent in bronchioloalveolar cell carcinoma (BAC) and a Phase I/II trial of Tarceva in combination with Avastin. In a phase II study Tarceva has shown effectiveness in brain cancer (glioma).

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Tarceva is a new form of anti-cancer treatment currently being tested in a variety of tumour types. It is a small molecule that works by blocking the activity of an enzyme called epidermal growth factor receptor (EGFR) tyrosine kinase, which helps communicate information within the cancer cell. EGFR, also known as HER1, is found on the surface of many tumour cells and may be involved in the growth and virulence of those cells. Tarceva is designed to inhibit the tyrosine kinase activity of the EGFR signaling pathway inside the cell, which may block tumour growth.

#### 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. 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 cancers.

#### About the Alliance

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>.

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.

Headquartered in Basel, Switzerland, Roche is one of the world's leading innovation-driven healthcare groups. Its core businesses are pharmaceuticals and diagnostics. Roche is number one in the global diagnostics market and is the leading supplier of pharmaceuticals for cancer and a leader

in virology and transplantation. As a supplier of products and services for the prevention, diagnosis and treatment of disease, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche employs roughly 65,000 people in 150 countries. The Group has alliances and research and development agreements with numerous partners, including majority ownership interests in Genentech and Chugai.

### **Roche in Oncology**

Within the last five years Roche has become the world's leading provider of anti-cancer treatments, supportive care products and diagnostics. Its oncology business includes an unprecedented three marketed products with survival benefit; Herceptin, MabThera and Xeloda, treating a range of malignancies - breast cancer, non-Hodgkin's lymphoma and colorectal cancer. Other key products include NeoRecormon (anaemia in various cancer settings), Bondronat (hypercalcemia of malignancy), Roferon-A (leukaemia, Kaposi's sarcoma, malignant melanoma, renal cell carcinoma) and Kytril (chemotherapy and radiotherapy-induced nausea and vomiting). A total of 2.9 billion Swiss francs in oncology product sales were recorded for the first six months of 2003.

Roche's products in development also promise survival benefit with Avastin. In a recent study Avastin increased survival duration by 30% when combined with first-line chemotherapy for patients with advanced colorectal cancer.

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).

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