(osi) pharmaceuticals

FDA Approves Tarceva-TM- For Patients with Advanced Non-Small Cell Lung Cancer; Only Targeted EGFR Therapy Shown to Improve Survival in Advanced Non-Small Cell Lung Cancer

MELVILLE, N.Y. & SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 18, 2004--OSI Pharmaceuticals, Inc. (Nasdaq: OSIP) and Genentech, Inc. (NYSE: DNA) announced today that the U.S. Food and Drug Administration (FDA) has approved, after priority review, Tarceva™ (erlotinib) for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after failure of at least one prior chemotherapy regimen. Tarceva™ is an oral tablet indicated for daily administration. Tarceva™ is the only drug in the epidermal growth factor receptor (EGFR) class to demonstrate in a Phase III clinical trial an increase in survival in advanced NSCLC patients. Tarceva™ will be available within five shipping days.

"The FDA approval of erlotinib marks an important new treatment option for patients in the United States with advanced non-small cell lung cancer after chemotherapy has failed," said Alan Sandler, M.D., associate professor of medicine at Vanderbilt University and medical director of the Thoracic Oncology Department. "Physicians will now be able to offer patients a new therapy that has been proven to increase survival and that is different from traditional cytotoxic chemotherapy treatment."

The FDA based its approval decision for Tarceva™ on results from a randomized double-blind, placebo-controlled pivotal Phase III trial of patients with second and third-line advanced NSCLC. In this pivotal study, patients receiving Tarceva™ had a median survival of 6.7 months compared to 4.7 months in patients who received placebo (a 42.5 percent improvement). A hazard ratio (HR) of 0.73 and a p-value of less than 0.001 were determined for comparisons of overall survival (HR of less than one indicates a reduction in the risk of death and a p-value of less than 0.05 indicates statistical significance). In addition, 31.2 percent of patients receiving Tarceva™ in the study were alive at one year versus 21.5 percent in the placebo arm.

Results from two earlier large, randomized, placebo-controlled clinical trials in first-line advanced NSCLC patients showed no clinical benefit with concurrent administration of Tarceva™ with doublet platinum-based chemotherapy (carboplatin and paclitaxel or gemcitabine and cisplatin) and its use is not recommended in that setting.

In the pivotal trial, the most common adverse reactions in patients receiving Tarceva™ were rash and diarrhea. Grade three/four rash and diarrhea occurred in nine and six percent of Tarceva™-treated patients, respectively. Rash and diarrhea each resulted in discontinuation of one percent of Tarceva™-treated patients. Six and one percent of patients needed dose reduction for rash and diarrhea, respectively. Historically, there have been infrequent reports of serious interstitial lung disease (ILD), including fatalities, in patients receiving Tarceva™ for treatment of NSCLC or other advanced solid tumors. In the Phase III trial, severe pulmonary reactions, including potential cases of interstitial lung disease, were infrequent (0.8 percent) and were equally distributed between treatment arms. The overall incidence of ILD in Tarceva™-treated patients from all studies was approximately 0.6 percent.

"This is a significant day for non-small cell lung cancer patients and their families," stated Colin Goddard, Ph.D., Chief Executive Officer of OSI Pharmaceuticals. "Tarceva™ offers a new kind of therapy for advanced lung cancer patients, not only providing improved survival, but doing so without many of the side effects associated with conventional chemotherapy."

"The FDA approval of Tarceva™ is the result of extraordinary effort and commitment by many employees at OSI and Genentech, clinical investigators, the FDA, and most importantly, the patients who volunteered to be part of the clinical trial that resulted in this approval," said Arthur D. Levinson, Ph.D., Genentech's chairman and chief executive officer.

Genentech does not expect Tarceva's approval specifically to affect its previously stated expectation of non-GAAP earnings of $0.80 to $0.83 for 2004.

About the Tarceva™ Filing

The Tarceva™ NDA was granted Pilot 1 Status under the FDA's Pilot 1 Program for Continuous Marketing Applications, a new program designed for investigational products that have been given Fast Track status, such as Tarceva™, and that have demonstrated significant promise in clinical trials as a therapeutic advance over available therapy for a disease or condition. Under Pilot 1 status, the FDA is committed to reviewing each unit of the NDA within six months of each unit submission. Tarceva™ is one of the first drugs to be granted and approved under the FDA's Pilot 1 program.

About the Tarceva™ Pivotal Trial

The pivotal trial for Tarceva™ included 731 patients with advanced NSCLC for whom one or more chemotherapy regimens had failed. The primary endpoint for the study was survival. In addition to achieving this primary endpoint, Tarceva™ also met all secondary endpoints of the trial. The global study was conducted by the National Cancer Institute of Canada Clinical Trials Group based at Queen's University in collaboration with OSI Pharmaceuticals.

About 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. It is estimated that more than 173,000 people will be diagnosed with lung cancer in the United States in 2004. 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 this country. NSCLC is the most common form of the disease and accounts for almost 80 percent of all lung cancers.

"When chemotherapy fails patients with advanced non-small cell lung cancer, they often feel like they are running out of options. Today, with the approval of Tarceva, patients not only have another option, but one that extends survival. That is something lung cancer patients don't often get offered," said Jane Reese-Coulbourne, acting executive director, ALCASE (Alliance for Lung Cancer Advocacy, Support and Education).

About Tarceva™

Tarceva™ is a small molecule designed to target the human epidermal growth factor receptor 1 (HER1) pathway, which is one of the factors critical to cell growth in NSCLC. HER1, also known as EGFR, is a component of the HER signaling pathway, which plays a role 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 may block tumor cell growth. A Phase III clinical trial of Tarceva™ has been completed in pancreatic cancer, and additional early-stage trials of Tarceva™ are being conducted in other solid tumors. For Tarceva™ full prescribing information, please call 1-877-TARCEVA or visit http://www.tarceva.com.

About OSI Pharmaceuticals

OSI Pharmaceuticals is a leading biotechnology company focused on the discovery, development, and commercialization of high-quality, next-generation oncology products that both extend life and improve the quality of life for cancer patients worldwide. OSI has a balanced pipeline of oncology drug candidates that includes both novel mechanism-based, gene-targeted therapies focused in the areas of signal transduction, apoptosis, and a next-generation cytotoxic chemotherapy agent. Tarceva™, OSI's flagship product, is the first OSI drug to obtain FDA approval. 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. OSI also established Prosidion Limited, an independently operated diabetes and obesity subsidiary based in the United Kingdom. For additional information about the company, please visit http://www.osip.com.

About Genentech BioOncology

Genentech is committed to changing the way cancer is treated by establishing a broad oncology portfolio of innovative, targeted therapies with the goal of improving patients' lives. The company is the leading provider of anti-tumor therapeutics in the United States. Genentech is leading clinical development programs for Rituxan® (Rituximab), Herceptin® (Trastuzumab), Avastin™ (bevacizumab), and Tarceva™ (erlotinib), and markets all four products in the United States, either alone (Avastin and Herceptin) or with Biogen Idec Inc. (Rituxan) or OSI Pharmaceuticals, Inc. (Tarceva). Genentech has licensed Rituxan, Herceptin, and Avastin to Roche for sale by the Roche Group outside of the United States.

The company has a robust pipeline of potential oncology therapies with a focus on four key areas: angiogenesis, apoptosis (i.e., programmed cell death), the HER pathway, and B-cell biology. A therapeutic antibody directed at the HER pathway is currently in Phase II trials and in early development are a small molecule directed at the hedgehog pathway, a therapy targeting apoptosis, and a humanized anti-CD20 antibody for hematology/oncology indications.

Genentech is a leading biotechnology company that discovers, develops, manufactures, and commercializes biotherapeutics for significant unmet medical needs. A considerable number of the currently approved biotechnology products originated from, or are based on, Genentech science. Genentech manufactures and commercializes multiple biotechnology products directly in the United States and licenses several additional products to other companies. 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.

Regarding OSI

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, OSI's and its collaborators' abilities to successfully develop and commercialize drug candidates, competition from other pharmaceutical companies, the ability to effectively market products, and other factors described in OSI Pharmaceuticals' filings with the Securities and Exchange Commission.

Regarding Genentech

The statement made in this press release relating to Genentech's 2004 non-GAAP earnings per share (EPS) is forward-looking and actual results could differ materially. Among other things, our 2004 non-GAAP EPS could be impacted by a number of factors, including FDA actions or delays, competition, pricing, new product approvals and launches, government reimbursement rates, the ability to supply product, product withdrawals, achieving sales revenue consistent with internal forecasts, unanticipated expenses such as litigation or legal settlement expenses or equity securities writedowns, costs of sales, R&D expenses, fluctuations in contract revenues and royalties, and fluctuations in tax and interest rates. Genentech disclaims any obligation and does not undertake to update or revise the forward-looking statement discussed in this press release.

CONTACT: OSI
Media and Investor Contact:
Kathy Galante, 631-962-2000
or
GNE Media Contact:
Kristina Becker, 650-467-6450
or
GNE Investor Contact:
Kathee Littrell, 650-225-1034
or
GNE Advocacy Relations:
Cheya Pope, 650-225-6334

SOURCE: OSI Pharmaceuticals, Inc.