

Genentech and OSI Pharmaceuticals Announce Topline Results from Phase III Study Evaluating the Combination of Avastin and Tarceva as Second-Line Treatment for Advanced Non-Small Cell Lung Cancer

SOUTH SAN FRANCISCO, Calif. & MELVILLE, N.Y.--(BUSINESS WIRE)--

Genentech, Inc. (NYSE:DNA) and OSI Pharmaceuticals, Inc. (Nasdaq:OSIP) today announced that a randomized Phase III study (BeTa Lung) evaluating Avastin[®] (bevacizumab) in combination with Tarceva[®] (erlotinib) in patients with advanced non-small cell lung cancer (NSCLC) whose disease had progressed following platinum-based chemotherapy did not meet its primary endpoint of improving overall survival compared to Tarceva in combination with placebo. However, there was clear evidence of clinical activity with improvements in the secondary endpoints of progression-free survival (PFS) and response rate when Avastin was added to Tarceva compared to Tarceva alone in this study.

Median survival was similar in both arms of BeTa Lung. No new or unexpected safety signals for either Avastin or Tarceva were observed in the study, and adverse events were consistent with those observed in previous NSCLC clinical trials evaluating the agents. The companies are further analyzing the study results and will submit the data for presentation at the 2008 Chicago Multidisciplinary Symposium in Thoracic Oncology in Chicago, Ill., November 13-15.

"We are disappointed this study did not show an improvement in survival for patients with advanced lung cancer who have a poor prognosis and a disease that is extremely difficult to treat. We are, however, encouraged to see the combination of Avastin and Tarceva had clear evidence of biological activity, and will fully analyze the data so that we can apply the insights to our ongoing lung cancer research," said Hal Barron, M.D., Genentech's senior vice president, Development and chief medical officer. "The results of this study do not affect Avastin or Tarceva's approved indications in advanced non-small cell lung cancer."

Avastin is currently approved as first-line treatment in combination with carboplatin and paclitaxel chemotherapy for patients with locally advanced, non-squamous, NSCLC based on a 25 percent improvement in overall survival compared to chemotherapy alone (hazard ratio 0.80).

Tarceva is currently approved as a treatment for patients with advanced NSCLC who have progressed following treatment with at least one prior chemotherapy regimen, based on a 37 percent improvement in overall survival compared to placebo (hazard ratio 0.73).

"The data from this study continue to support the role of Tarceva as an important treatment option for advanced lung cancer patients," said Gabriel Leung, President, OSI Oncology. "Median survival in the Tarceva and placebo group in this second-line study was 9.2 months. As expected, this exceeded the median survival of 6.7 months seen in the Tarceva registration study, BR.21, that included patients treated in both the second- and third-line settings. We look forward to results of SATURN, a Phase III trial evaluating single-agent Tarceva as a first-line maintenance therapy in NSCLC patients whose disease has not progressed following treatment with chemotherapy."

A second study (ATLAS) is evaluating the combination of Avastin and Tarceva as a potential first-line maintenance therapy for advanced non-small cell lung cancer patients whose disease has not progressed following initial treatment with Avastin in combination with chemotherapy. Results are expected in the first half of 2009.

About BeTa Lung

BeTa Lung is a global, multicenter, placebo-controlled, randomized, double-blinded Phase III study that enrolled 636 patients with advanced NSCLC. Patients must have experienced disease progression during or following first-line standard chemotherapy or chemoradiotherapy. Patients who had received previous treatment with an epidermal growth factor receptor (EGFR) inhibitor or anti-angiogenesis agent were not eligible for this trial. In order to evaluate patients who are often excluded from clinical trials, patients with treated brain metastases, tumors of squamous cell histology that were not centrally located in the lung, and patients taking blood-thinning medications were eligible for this trial. Patients were randomized to receive Tarceva in combination with Avastin or Tarceva in combination with placebo. The primary endpoint of the study was improvement in overall survival. Secondary endpoints included progression-free survival, objective response and an evaluation of exploratory biomarkers.

About Non-Small Cell Lung Cancer

According to the American Cancer Society, lung cancer is the single largest cause of cancer deaths among men and women in the United States and is responsible for nearly 30 percent of cancer deaths in this country. The American Cancer Society estimates that in 2008 more than 215,000 Americans will be diagnosed with lung cancer and 162,000 will die of the disease. NSCLC is the most common type of lung cancer.

About Avastin

Avastin is a biologic antibody designed to specifically inhibit the vascular endothelial growth factor (VEGF) protein that plays an important role in the development and maintenance of blood vessels, a process known as angiogenesis. VEGF is a potent activator of angiogenesis throughout the lifecycle of a tumor. By inhibiting VEGF, Avastin is designed to interfere with the blood supply to a tumor, which is thought to be critical to a tumor's ability to grow and spread in the body (metastasize).

Avastin is indicated for the first- and second-line treatment of metastatic colorectal cancer in combination with intravenous 5-FU-based chemotherapy and for the first-line treatment of unresectable, locally advanced, recurrent or metastatic non-squamous, NSCLC in combination with carboplatin and paclitaxel. For more information on angiogenesis, visit <http://www.gene.com>.

Avastin Safety

The most serious side effects associated with Avastin across all trials were gastrointestinal (GI) perforation, slow wound healing, severe bleeding, formation of an abnormal passage from parts of the body to another part, blood clots, severe high blood pressure, nervous system and vision disturbances, reduced white blood cell counts, kidney malfunction, and congestive heart failure.

The most common serious adverse events that may have occurred for Avastin for first- and second-line metastatic colorectal cancer and first-line non-small cell lung cancer included reduced white blood cell counts, tiredness, high blood pressure, infection, severe bleeding, weakness, abdominal pain, pain, blood clots, a brief loss of consciousness, diarrhea, constipation, nausea, vomiting, dehydration, blockage of the bowel, numbness and tingling in fingers and toes, nervous system disturbances, and headache.

For full Prescribing Information and Boxed Warnings on Avastin, visit <http://www.avastin.com>.

About Tarceva

Tarceva is a small molecule designed to target the EGFR pathway, which is one of the factors critical to cell growth in NSCLC and pancreatic cancers. Tarceva is designed to inhibit the tyrosine kinase activity of the EGFR signaling pathway inside the cell.

Tarceva is FDA-approved for use as a monotherapy in patients with locally advanced or metastatic NSCLC whose disease has progressed after one or more courses of chemotherapy (at a recommended dose of 150 mg/day). Results from two, multicenter, placebo-controlled, randomized, Phase III trials conducted in first-line patients with locally advanced or metastatic NSCLC showed no clinical benefit with the concurrent administration of Tarceva with platinum-based chemotherapy (carboplatin and paclitaxel or gemcitabine and cisplatin) and its use is not recommended in that setting.

Tarceva is also approved in combination with gemcitabine for the treatment of locally advanced or metastatic pancreatic cancer in patients who have not received previous chemotherapy (at a recommended dose of 100mg/day).

Tarceva Safety Profile

There have been infrequent reports of interstitial lung disease (ILD)-like events, including fatalities in patients receiving Tarceva. In patients receiving Tarceva plus gemcitabine for pancreatic cancer, myocardial infarction/ischemia, cerebrovascular accident, and micro-angiopathic hemolytic anemia with thrombocytopenia have occurred. Cases of hepatic failure, hepatorenal syndrome, acute renal failure (all including fatalities), and renal insufficiency have been reported during use of Tarceva. While receiving Tarceva therapy, women should be advised against becoming pregnant or breastfeeding. The most common adverse reactions in patients with NSCLC receiving Tarceva were rash and diarrhea. The most common adverse reactions in patients with pancreatic cancer receiving Tarceva plus gemcitabine were fatigue, rash, nausea, anorexia, and diarrhea.

For full prescribing information, please call 1-877-TARCEVA or visit <http://www.tarceva.com>.

About Genentech

Founded more than 30 years ago, Genentech is a leading biotechnology company that discovers, develops, manufactures and commercializes medicines for patients with significant unmet medical needs. The company has headquarters in South San

Francisco, California and is listed on the New York Stock Exchange under the symbol DNA. For additional information about the company, please visit <http://www.gene.com>.

About OSI Pharmaceuticals

OSI Pharmaceuticals is committed to "shaping medicine and changing lives" by discovering, developing and commercializing high-quality and novel pharmaceutical products designed to extend life and/or improve the quality of life for patients with cancer and diabetes/obesity. The Company's oncology programs are focused on developing molecular targeted therapies designed to change the paradigm of cancer care. OSI's diabetes/obesity efforts are committed to the generation of novel, targeted therapies for the treatment of type 2 diabetes and obesity. OSI's flagship product, Tarceva® (erlotinib), is the first drug discovered and developed by OSI to obtain FDA approval and the only EGFR inhibitor to have demonstrated the ability to improve survival in both NSCLC and pancreatic cancer patients in certain settings. OSI markets Tarceva through partnerships with Genentech, Inc. in the United States and with Roche throughout the rest of the world. For additional information about OSI, please visit (<http://www.osip.com>).

OSI Safe Harbor Statement

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 results from, and the ability to complete, 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.

Source: Genentech, Inc. and OSI Pharmaceuticals, Inc.