

Early Clinical Data Evaluating the Combination of Avastin and Tarceva Yield Initial Promising Results in Several Cancers

- Researchers Present Phase I/II Data Showing Improved Progression-Free Survival in Patients With Metastatic Kidney Cancer and Relapsed Non-Small Cell Lung Cancer -

NEW ORLEANS, June 5 /PRNewswire-FirstCall/ -- Genentech, Inc. (NYSE: DNA) and OSI Pharmaceuticals (Nasdaq: OSIP) today announced results from Phase I/II clinical studies examining the combination of Avastin™ (bevacizumab) and the investigational small molecule Tarceva™ (erlotinib HCl) in the treatment of metastatic renal cell carcinoma (kidney cancer) and relapsed non-small cell lung cancer (NSCLC). These trials are important because patients received no chemotherapy and instead were treated with a combination of two therapies targeted at two distinct avenues of growth in cancer: angiogenesis and EGFR signaling. The results were presented at the 40th Annual Meeting of the American Society of Clinical Oncology (ASCO).

Avastin is a therapeutic antibody designed to inhibit angiogenesis, the process by which new blood vessels develop, which is necessary to support tumor growth and metastasis. Avastin is currently approved in the United States for use in combination with intravenous 5-Fluorouracil (5-FU)-based chemotherapy as a treatment for first-line metastatic colorectal cancer. Tarceva, an investigational therapy, is an oral, once-a-day, small molecule designed to target the human epidermal growth factor receptor 1 (HER1/EGFR) pathway, which is one of the factors critical to cell growth in many cancers.

"As cancer patients live longer, quality of life and avoiding toxic side effects become more important," said Gwen Fyfe, M.D., Genentech's vice president, Clinical Hematology/Oncology. "Evaluating the combination of Avastin and Tarceva in certain cancers is representative of our strategy to inhibit tumor growth by simultaneously targeting different cancer pathways. We are encouraged by the response and progression-free survival data observed in these studies of patients with advanced kidney and lung cancers and believe these data support future evaluation of this combination in multiple tumor types."

In addition to the combination studies in recurrent NSCLC and metastatic kidney cancer, preliminary data from studies evaluating the combination of Avastin plus Tarceva in metastatic breast cancer and recurrent and/or metastatic head and neck cancer will be presented at this year's ASCO meeting.

Phase II Study of Tarceva and Avastin in Metastatic Renal Cell Carcinoma (Abstract #4502)

This single-arm Phase II study, presented by John Hainsworth, M.D., of the Sarah Cannon Cancer Center in Nashville, Tenn., focused on preliminary results from 62 patients with metastatic renal cell carcinoma (kidney cancer) treated with a combination of Avastin and the investigational drug Tarceva. Results of this study will be highlighted by ASCO in a "Targeted Therapies" press conference at 9:00 a.m. CDT on Sunday, June 6. These results add to the data generated by the Phase II study of single-agent Avastin in metastatic renal cell carcinoma, which were presented at the 2002 ASCO meeting and published in the *New England Journal of Medicine* in 2003.

At the time of analysis, 62 patients had been enrolled in the study and 58 were evaluable for response. The authors reported that at eight weeks, 21 percent of patients (12/58) experienced an objective response (defined as a 50 percent or greater decrease in the size of a tumor) to the combined therapy and 66 percent (38/58) experienced a minor response or disease stabilization. At six months, 67 percent of the evaluable patients (39/58) had progression-free survival and after one year, 50 percent of patients (29/58) had progression-free survival. Overall survival after six months was 92 percent and after one year was 81 percent.

The Grade 3 or 4 adverse events observed in the study included hypertension (8 percent, 5/58), diarrhea (10 percent, 6/58), rash (13 percent, 8/58), nausea/vomiting (10 percent, 6/58), bleeding (5 percent, 3/58), pruritus (3 percent, 2/58), proteinuria (3 percent, 2/58), neuropathy (3 percent, 2/58) and edema (2 percent, 1/58).

Phase I/II Study of Avastin and Tarceva in Recurrent Non-Small Cell Lung Cancer (Abstract #2000)

Alan Sandler, M.D., of Vanderbilt-Ingram Cancer Center, reported on results from a multicenter Phase I/II study designed to evaluate the combination of Avastin and Tarceva in the treatment of recurrent non-small cell lung cancer (NSCLC) patients.

To date, 40 patients have been enrolled in the trial. At the time of analysis, median survival was 12.6 months, median progression-free survival was 7 months and the estimated one-year survival was 54 percent. Partial responses were observed in 20 percent of patients (8/40) and an additional 65 percent of patients (26/40) achieved stable disease in the study. The most

frequent adverse events reported were mild-to-moderate rash (93 percent, 37/40), diarrhea (78 percent, 31/40) and proteinuria (18 percent, 7/40).

Traditionally patients with relapsed NSCLC are treated with chemotherapy, which may be very poorly tolerated by some advanced patients. If randomized, Phase III trials of Avastin plus Tarceva show clinical benefit, this combination could provide an important treatment option that does not include chemotherapy.

About Avastin

Avastin is a therapeutic antibody designed to inhibit VEGF, a protein that plays an important role in tumor angiogenesis and maintenance of existing tumor vessels. By binding to VEGF, Avastin is designed to interfere with the blood supply to tumors, a process that is critical to tumor growth and metastasis. Avastin received approval by the U.S. Food and Drug Administration (FDA) on February 26, 2004, to be used in combination with intravenous 5-Fluorouracil-based chemotherapy as a treatment for first-line metastatic colorectal cancer. For full prescribing information, Boxed Warnings on Avastin and information about angiogenesis, visit www.gene.com. For more information about Avastin, visit www.avastin.com.

Earlier this year, the National Comprehensive Cancer Network (NCCN), an alliance of 19 of the world's leading cancer centers, updated their Colorectal Clinical Practice Guidelines and added Avastin in combination with 5-Fluorouracil-based regimens -- including those using oxaliplatin or irinotecan -- to its list of treatment options for first-line advanced colon or rectal cancer.

Based on data showing that VEGF plays a broad role in a range of cancers, Genentech is pursuing a late-stage clinical development program with Avastin evaluating its potential use in various cancers, including renal cell (kidney), breast and non-small cell lung cancers. Avastin is also being evaluated in earlier stage trials as a potential therapy in prostate, ovarian and several other types of solid tumor cancers as well as in hematologic malignancies and melanoma.

Avastin Safety Profile

The addition of Avastin to chemotherapy is generally well tolerated. In Genentech-sponsored studies, the most serious adverse events associated with Avastin were infrequent, and included gastrointestinal perforation, wound healing complications, hemorrhage, hypertensive crisis, nephrotic syndrome, and congestive heart failure. The most common Grade 3-4 adverse events (occurring in greater than 2 percent of patients in the Avastin arm, compared to the control group) were asthenia, pain, hypertension, diarrhea and leukopenia. The most common adverse events (occurring in greater than 2 percent of patients in the Avastin arm, compared to the control group) of any severity were asthenia, pain, abdominal pain, headache, hypertension, diarrhea, nausea, vomiting, anorexia, stomatitis, constipation, upper respiratory infection, epistaxis, dyspnea, exfoliative dermatitis and proteinuria.

About Tarceva

Tarceva is an investigational 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 many cancers. HER1, also known as EGFR, is potentially a key 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. The Tarceva pivotal trial was a randomized Phase III study that assessed Tarceva as a single agent in patients with stage III/IV refractory NSCLC and showed an improvement in survival compared to placebo. Results of a Phase III trial of Tarceva in pancreatic cancer are expected in the second half of 2004. Early-stage trials of Tarceva are being conducted in other solid tumors, such as ovarian, colorectal, head and neck, kidney, brain and gastrointestinal cancers. Tarceva is being developed by a global alliance of Genentech, OSI Pharmaceuticals and Roche.

A preliminary analysis of data from the Tarceva pivotal trial showed that the toxicities reported were as expected in patients receiving Tarceva compared to those receiving placebo. In line with previous clinical studies, events that occurred more often with patients treated with Tarceva included mainly mild to moderate diarrhea and rash.

About Genentech

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), and Avastin™ (bevacizumab) and markets all three products in the United States either alone (Avastin, which it recently launched in the United States, and Herceptin) or with Biogen Idec Inc. (Rituxan). 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. Potential oncology therapies directed at the HER pathway

include Tarceva™ (erlotinib) and a therapeutic antibody currently in Phase II trials. Also 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. Eighteen of the currently approved biotechnology products originated from or are based on Genentech science. Genentech manufactures and commercializes 13 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 additional information about the company, please visit <http://www.gene.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 and apoptosis and next-generation cytotoxic chemotherapy agents. 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. For additional information about OSI, please visit <http://www.osip.com>.

For full Avastin prescribing information, including Boxed Warnings, please call 650-225-7739 or visit <http://www.gene.com>.

The statement made in this press release relating to the expected time frame for data availability from the Tarceva Phase III trial in pancreatic cancer is forward-looking and actual results could differ materially. Among other things, the time frame could be affected by unexpected safety issues, the length of time to achieve study endpoints, additional time requirements for data analysis or discussions with the FDA.

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 successful marketing of products, product pricing and third-party reimbursement, 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, and other factors described in OSI's 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.

SOURCE Genentech, Inc.; OSI Pharmaceuticals, Inc.

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