GENENTECH RECEIVES COMPLETE RESPONSE LETTER FROM FDA FOR AVASTIN® IN METASTATIC BREAST CANCER

SOUTH SAN FRANCISCO, Calif. -- September 11, 2006 -- Genentech, Inc. today announced that it received a Complete Response Letter from the U.S. Food and Drug Administration (FDA) for a supplemental Biologics License Application (sBLA) for Avastin® with chemotherapy in first-line metastatic breast cancer. The FDA has requested a substantial safety and efficacy update from the E2100 trial, including an independent review of patient scans for progression free survival, the study’s primary endpoint. Issuance of the Complete Response Letter satisfies the FDA's product review performance goals specified under the Prescription Drug User Fee Act. A new six-month review period will begin once the additional information requested is submitted to the FDA.

The sBLA submitted to the FDA on May 23, 2006 was based on interim data from the E2100 trial. The study was sponsored by the National Cancer Institute (NCI), part of the National Institutes of Health (NIH), under a Cooperative Research and Development Agreement between NCI and Genentech and was conducted by a network of researchers led by the Eastern Cooperative Oncology Group (ECOG). The FDA has communicated to Genentech that they now expect the information from this cooperative group trial to be audited and summarized in a manner typically used for a company-sponsored trial. This expectation is different from the understanding that Genentech had when the sBLA was submitted and will require the re-collection of information from ECOG study sites.

“We are disappointed that this will cause a delay in the review of our application, as there is a great unmet medical need for women with metastatic breast cancer. Based on the scope of this request, we anticipate we will be able to resubmit the application to the FDA by mid-2007,” said Hal Barron, Genentech senior vice president, Development and chief medical officer. “We believe E2100 demonstrates significant clinical benefit and we will work with ECOG and the FDA to help bring Avastin to patients with metastatic breast cancer.”
Genentech is pursuing a broad development program for Avastin that currently includes 130 clinical trials across 25 different types of cancer. As part of this program, Genentech is conducting two Phase III studies of Avastin plus chemotherapy in both first- and second-line metastatic breast cancer (RIBBON-1 and RIBBON-2). A third Phase III trial (AVADO) in first-line metastatic breast cancer is being conducted by Roche.

**About E2100**

Patients enrolled in E2100 were randomized to receive weekly treatment with paclitaxel, with or without Avastin administered every two weeks. In addition to patients with HER2-negative metastatic breast cancer, patients with HER2-positive tumors were enrolled in the study only if they had received prior treatment with Herceptin® (Trastuzumab) or were unable to receive treatment with Herceptin. Patients who had received adjuvant paclitaxel within the previous 12 months, patients with a prior history of blood clots or who were receiving blood thinners, and patients with brain metastases were excluded from the study. Results from the E2100 trial were first presented at the 2005 American Society of Clinical Oncology Annual Meeting.

**E2100 Safety Analysis**

In the E2100 study, adverse events were similar to those seen in previous trials of Avastin plus chemotherapy. No new toxicities were identified as being associated with Avastin. Fatal events (Grade 5) occurred in less than 1 percent of patients enrolled in E2100. Grade 3/4 adverse events that occurred more often (equal to or greater than 5 percent) in the Avastin plus paclitaxel arm than in the paclitaxel alone arm included hypertension and sensory neuropathy. Grade 3/4 sensory neuropathy occurred in 23 percent of patients in the Avastin plus paclitaxel arm and in 17 percent of patients in the paclitaxel alone arm. Neuropathy is known to be associated with duration of paclitaxel therapy. Adverse events associated with Avastin including symptomatic congestive heart failure, serious bleeding and arterial thromboembolic events were not different in terms of incidence or severity relative to what has been previously observed in Avastin clinical trials. In addition, there was no increase in the incidence of Grade 3/4 venous thromboembolic events with the addition of Avastin to paclitaxel in this study.

**About Avastin**

Avastin is a therapeutic antibody designed to inhibit Vascular Endothelial Growth Factor
VEGF, a protein that plays an important role in tumor angiogenesis and maintenance of existing tumor vessels. By inhibiting VEGF, Avastin is designed to interfere with the blood supply to a tumor, a process that is thought to be critical to a tumor’s growth and metastasis. For full prescribing information and boxed warnings on Avastin and information about angiogenesis, visit http://www.gene.com. For more information on Avastin, visit http://www.avastin.com.

Avastin, in combination with intravenous 5-FU-based chemotherapy, is indicated for first- or second-line treatment of patients with metastatic carcinoma of the colon or rectum. The FDA first approved Avastin on February 26, 2004 as a first-line treatment for metastatic colorectal cancer in combination with intravenous 5-FU-based chemotherapy. Approval was based on data from two trials. The pivotal trial was a large, placebo-controlled, randomized study that demonstrated a prolongation in the median survival of patients treated with Avastin plus the IFL (5-FU/leucovorin/CPT-11) chemotherapy regimen by approximately five months, compared to patients treated with the IFL chemotherapy regimen alone (20.3 months versus 15.6 months). The addition of Avastin to IFL improved overall survival by 52 percent (based on a hazard ratio of 0.66). In addition, this study demonstrated an improvement in progression-free survival of more than four months (10.6 months in the Avastin/IFL arm compared to 6.2 months in the IFL-alone arm).

Avastin Safety Profile

Avastin has a well-established safety profile. In Genentech-sponsored studies, the most serious adverse events associated with Avastin were gastrointestinal perforation, wound healing complications, hemorrhage, arterial thromboembolic events, hypertensive crisis, nephrotic syndrome and congestive heart failure. The most common Grade 3/4 adverse events (occurring in greater than two 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 two 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 the Avastin Development Program

Based on data showing that VEGF may play an important role in a range of cancers, Genentech is pursuing a broad development program for Avastin. Avastin is being evaluated in Phase III clinical trials for its potential use in adjuvant and metastatic colorectal, renal cell (kidney), breast, pancreatic, non-small cell lung, prostate and ovarian cancers. Avastin is also being evaluated in earlier stage trials as a potential therapy in a variety of solid tumor cancers and hematologic malignancies. In April 2006, Genentech submitted an sBLA for Avastin plus platinum-based chemotherapy for first-line treatment of advanced non-small cell lung cancer other than predominant squamous histology. For further information about Avastin clinical trials, please call 888-662-6728.

About VEGF and Tumor Angiogenesis

The link between angiogenesis and cancer growth has been discussed by many researchers for decades. It wasn't until 1989 that a key growth factor influencing the process, VEGF, was discovered by Napoleone Ferrara, M.D., a staff scientist at Genentech. Dr. Ferrara and his team at Genentech cloned VEGF, providing some of the first evidence that a specific angiogenic growth factor existed. This research was published in the journal Science in 1989. Dr. Ferrara then created a mouse antibody to this protein.

In 1993, in a study published in Nature, Dr. Ferrara and his team demonstrated that the antibody directed against VEGF could suppress angiogenesis and tumor growth in preclinical models, providing compelling evidence that VEGF can play a critical role in tumor growth. Clinical studies with a humanized version of the antibody, Avastin, began in 1997.

About Breast Cancer

According to the American Cancer Society, an estimated 212,920 women will be diagnosed with breast cancer along with a much smaller number of men, and approximately 40,970 women will die of the disease in the United States in 2006. Breast cancer is the most common cause of cancer among women in the United States, and a woman is diagnosed with breast cancer in the United States every three minutes.
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 conducting 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).

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. An investigational antibody directed at the HER pathway is currently in Phase II trials. In early development, are a small molecule directed at the hedgehog pathway and an investigational agent targeting apoptosis.

Founded 30 years ago, 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 listed on the New York Stock Exchange under the symbol DNA. For additional information about the company, please visit http://www.gene.com.

For the full prescribing information for Tarceva and the full prescribing information and Boxed Warnings for Rituxan, Herceptin, and Avastin, please visit http://www.gene.com.

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This press release contains forward-looking statements regarding the timing for re-submission of the Avastin metastatic breast cancer sBLA and bringing Avastin to metastatic breast cancer patients. Such statements are predictions and involves risks and uncertainties such that the actual results may differ materially. Among other things, the timing for resubmitting the Avastin sBLA could be affected by unexpected safety, efficacy or manufacturing issues, availability or sufficiency of study data, additional time requirements for data preparation, collection or analyses, coordination with third parties or decision-making, need for additional data or clinical studies, discussions with the FDA, and
FDA actions or delays; bringing Avastin to patients could be affected by all of the foregoing and by failure to receive or maintain FDA approval, competition, reimbursement, coverage, pricing, the ability to supply product, product withdrawal, new product approvals and launches, intellectual property or contract rights and higher than anticipated costs of sales or other expenses. Please also refer to Genentech's periodic reports filed with the Securities and Exchange Commission. Genentech disclaims, and does not undertake, any obligation to update or revise the forward-looking statements in this press release.