



NEWS RELEASE

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FDA APPROVES HERCEPTIN[®] FOR THE ADJUVANT TREATMENT OF HER2-POSITIVE NODE-POSITIVE BREAST CANCER

*-- Herceptin Significantly Reduced the Risk of Breast Cancer Recurrence
by 52 Percent in Pivotal Studies --*

*-- Only Targeted Biologic Therapy Approved for Use in Adjuvant and Metastatic
HER2-positive Breast Cancer --*

SOUTH SAN FRANCISCO, Calif. -- Nov. 16, 2006 -- Genentech, Inc. (NYSE: DNA) announced today that the U.S. Food and Drug Administration (FDA) approved Herceptin[®] (Trastuzumab), as part of a treatment regimen containing doxorubicin, cyclophosphamide, and paclitaxel, for the adjuvant treatment of HER2-positive node-positive breast cancer. Adjuvant therapy is given to women with early-stage (localized) breast cancer who have had initial treatment – surgery with or without radiation therapy – with the goal of reducing the risk of cancer recurrence and/or the occurrence of metastatic disease.

The FDA approval was based on data from an interim joint analysis of more than 3,500 patients enrolled in two Phase III clinical trials. These results showed that the addition of Herceptin to standard adjuvant therapy significantly reduced the risk of breast cancer recurrence, the primary endpoint of the studies, by 52 percent (or a hazard ratio of 0.48) in women with HER2-positive breast cancer, compared to those patients who received standard adjuvant therapy alone.

“The results of the joint analysis show that, for women with early-stage HER2-positive breast cancer, the addition of Herceptin to chemotherapy reduces the relative risk of breast cancer recurrence by approximately half, which translates into fewer women dying from one of the most aggressive types of breast cancer,” said Edward Romond, M.D., Professor of Medicine, Division of Hematology/Oncology at the University of Kentucky. “This is the largest improvement in outcome for any group of women with breast cancer in 25 years.”

“Our work with Herceptin exemplifies our commitment to developing the right drug for the right patient. We designed Herceptin for the approximately 25 percent of women whose breast cancers overexpress HER2 because we believed that we could make a significant impact for these patients battling a very aggressive, difficult-to-treat disease,” said Susan Desmond-Hellmann, M.D., M.P.H., Genentech’s president, product development. “These adjuvant studies showed that, in women with HER2-positive lymph node-positive breast cancer, Herceptin reduces the risk of developing metastatic disease, which could benefit thousands of lives worldwide each year.”

“This approval also highlights a first step in a major initiative to conduct studies of Genentech targeted therapies in earlier stages of disease where they have the potential to have the greatest impact,” added Desmond-Hellmann.

After three-and-a-half years in the study, 87 percent of women treated with Herceptin plus chemotherapy were disease free, compared to 71 percent of women treated with chemotherapy alone. A survival analysis conducted after patients had been followed for a median of 24 months showed a 33 percent reduction in the risk of death (based on a hazard ratio of 0.67), which is equivalent to a 49 percent improvement in overall survival.

Each study had an independent external Data Monitoring Committee (DMC) that reviewed data from the studies, including cardiac safety data, on a regular basis. According to the investigators, serious or life-threatening (and in rare cases, fatal) cardiac events, most commonly congestive heart failure (weakening of the heart muscle), occurred approximately 3 to 4 percent more often in the Herceptin plus standard therapy arms than in the standard therapy alone arms. Other adverse events reported in both studies included dyspnea and interstitial pneumonitis, which occurred at a rate of less than 1 percent.

“Today’s approval is wonderful news for women with early-stage HER2-positive breast cancer and another significant milestone in the Herceptin story,” said Fran Visco, president of the National Breast Cancer Coalition. “Thanks to the thousands of breast cancer patients, clinical investigators, the FDA, Genentech and advocates, who have all played critical roles in Herceptin’s development, we now have a treatment option that represents a major advance for women with HER2-positive breast cancer before the disease has metastasized. We look forward to continuing our collaboration with Genentech on future Herceptin research.”

Additional Background on the Joint Analysis Studies

The two Phase III trials were sponsored by the National Cancer Institute (NCI), part of the National Institutes of Health, and conducted by a network of researchers led by the National Surgical Adjuvant Breast and Bowel Project (NSABP) and the North Central Cancer Treatment Group (NCCTG), in collaboration with the Cancer and Leukemia Group B, the Eastern Cooperative Oncology Group and the Southwest Oncology Group.

These randomized, controlled trials studied four cycles of doxorubicin (adriamycin) and cyclophosphamide followed by paclitaxel, either every three weeks or weekly for 12 weeks, compared with the same regimen plus 52 weeks of Herceptin beginning with the first dose of paclitaxel.

The joint analysis results were first presented at the 41st Annual Meeting of the American Society of Clinical Oncology (ASCO) in May 2005 and subsequently published in *The New England Journal of Medicine* (NEJM) in October 2005.

About Herceptin

Herceptin is a targeted therapeutic antibody treatment for women who have tumors that overexpress the human epidermal growth factor receptor 2 (HER2) protein. HER2-positive breast cancer is an especially aggressive form of the disease that affects approximately one-fourth of women with breast cancer. Research has shown that women with HER2-positive breast cancer have a greater likelihood of recurrence, poorer prognosis and decreased survival compared to women with HER2-negative breast cancer. Special testing is required to identify women who have HER2-positive breast cancer and who may be candidates for treatment with Herceptin.

Herceptin is the only targeted biologic therapy approved for treatment of HER2-positive breast cancer in the adjuvant and metastatic settings. Herceptin first received FDA approval in September 1998 for use in women with metastatic breast cancer. In this setting, it is indicated for treatment of patients both as a first-line therapy in combination with paclitaxel and as a single agent in second- and third-line therapy.

In clinical trials of HER2-positive metastatic breast cancer patients, Herceptin in combination with chemotherapy (paclitaxel) was the first anti-HER2 agent to demonstrate an improvement in survival in a Phase III trial. In December 2001, Genentech received FDA

approval to include, in the product label, data that showed an improved median overall survival for women with HER2-positive metastatic breast cancer treated initially with Herceptin and chemotherapy, compared to chemotherapy alone (median 25.1 months compared to 20.3 months).

Herceptin Safety Profile

Herceptin administration can result in left ventricular dysfunction and congestive heart failure (CHF). The incidence and severity of left ventricular cardiac dysfunction/CHF were highest in patients who received Herceptin concurrently with anthracycline-containing chemotherapy regimens.

Herceptin should be discontinued in patients receiving adjuvant therapy for breast cancer who develop a clinically significant decrease in left ventricular function. In patients with metastatic breast cancer who develop a clinically significant decrease in left ventricular function, discontinuation of Herceptin should strongly be considered.

Serious infusion reactions and pulmonary toxicity have occurred; rarely these have been fatal. Discontinuation of Herceptin should be strongly considered for infusion reactions manifesting as anaphylaxis, angioedema, pneumonitis, or acute respiratory distress syndrome.

Exacerbation of chemotherapy-induced neutropenia has also occurred.

The most common adverse reactions associated with Herceptin use were fever, nausea, vomiting, infusion reactions, diarrhea, infections, increased cough, headache, fatigue, dyspnea (shortness of breath), rash, neutropenia (decrease in the number of neutrophils, a type of white blood cell), anemia, and myalgia (muscle pain).

About Breast Cancer

According to the American Cancer Society, 212,920 women in the United States will be diagnosed with breast cancer in 2006, and 40,970 will die from the disease. Excluding skin cancer, breast cancer is the most common form of cancer among women and the second-leading cancer killer among women, after lung cancer. The chance of a woman having invasive breast cancer some time during her life is about 1 in 8.

The chance of dying from breast cancer is about 1 in 33. Breast cancer death rates are going down. This decline is probably the result of finding the cancer earlier and improved

treatment.

Genentech's Commitment to Patient Access

Genentech is committed to assisting eligible patients in accessing our therapies for approved indications, regardless of their ability to pay. Although Genentech's products are covered by most government and private insurance, Genentech established the Genentech® Access to Care Foundation (GATCF) in 1990 for its marketed products. GATCF donates product to eligible patients in the United States who are uninsured or deemed uninsured due to payor denial, except for Pulmozyme® (dornase alfa, recombinant), which is covered by the Genentech Endowment for Cystic Fibrosis. In 2005 alone, GATCF supported over 18,000 patients by providing approximately \$200 million of free product. In addition, Genentech recently doubled to \$50 million its donation to several independent public charities that provide financial assistance to eligible patients who cannot access needed medical treatment due to co-pay costs. To learn more about potential financial assistance options, patients can speak with an Alternative Funding Specialist from Genentech's Single Point of Contact (SPOC) group by calling 866-724-9394 or visiting <http://www.SPOCOnline.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 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). For sale outside of the United States, Genentech has licensed Rituxan, Herceptin, and Avastin to Roche, and OSI Pharmaceuticals has licensed Tarceva to Roche.

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 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>.

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For full prescribing information, including Boxed WARNINGS for Herceptin, please call 800-821-8590 or visit <http://www.gene.com>.