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This press release was updated December 12, 2006, to include regional lymph nodes as part of the approval.

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FDA Expands Use of Herceptin for Early Stage Breast Cancer After Primary Therapy

The U. S. Food and Drug Administration (FDA) today expanded the approved use of Herceptin, a biological cancer drug. The new indication is for Herceptin, in combination with other cancer drugs, for the treatment of HER2 positive breast cancer after surgery (lumpectomy or mastectomy). FDA granted priority review to the supplemental application for Herceptin.

Herceptin is a targeted therapy against the HER2 protein on cancer cells. When an excessive amount of HER2 protein is present, it causes cancer cells to grow more rapidly and standard chemotherapy may be less effective. In 1998, FDA approved Herceptin for the treatment of metastatic breast cancer (cancer that has spread to other sites in the body). Today's approval expands its use to women with cancer in the breast and regional lymph nodes, which have been removed with surgery. Herceptin should only be prescribed for women diagnosed with HER2 positive breast cancer.

"This is especially good news for women who have breast cancer caused by excessive amounts of the HER-2 protein because this cancer typically has a poor prognosis," said Dr. Steven Galson, Director for FDA's Center for Drug Evaluation and Research.

The two studies leading to this new approved indication were conducted by the National Cancer Institute-sponsored Cooperative Groups, a multicenter clinical trials group. Patients in both trials received standard chemotherapy after surgery for breast cancer; approximately half the patients were also given Herceptin. The results from both trials, which included information on nearly 4,000 women, were combined and analyzed in 2005.

Due to positive results, the National Cancer Institute, a part of the National Institutes of Health, ended the studies early. The results showed that women who received Herceptin combined with chemotherapy had fewer relapses (return of breast cancer) for up to three years after surgery. The estimated three-year disease-free rates were 87 percent in women receiving Herceptin and chemotherapy and 75 percent in those receiving chemotherapy alone. It is too soon to know whether Herceptin combined with chemotherapy will increase the cure rate or lower the risk of death from breast cancer.

In the United States there are an estimated 212, 920 new cases of breast cancer and about 40,970 related deaths each year. Approximately 25 percent of women with breast cancer will have tumors that produce excessive amounts of HER2 protein.

The most serious side effect of Herceptin is heart failure (weakening of the heart muscle) that requires medical treatment. Due to the risk of heart disease, only certain patients should receive the drug, including:

- Only patients whose tumors are HER2 Positive
- Patients who do not have heart failure or weak heart muscle (cardiomyopathy). Patients must be screened for heart function before beginning and during Herceptin treatment.

Less common but serious side effects include infusion reactions (chills, fever, shortness of breath) that rarely are accompanied by lung problems, low white blood counts, and low red blood cell counts.

Herceptin (trastuzumab) is manufactured by Genentech, Inc, San Francisco, CA.

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