FDA Approves New Treatment Option For The Adjuvant Treatment Of HER2-Positive Node-Positive Breast Cancer

(NAPSA)—When Tammy Padgett, a young mother of two, was diagnosed with breast cancer in 2001 after feeling a lump in her breast, she was concerned about her diagnosis and how it would affect her future and family. After testing, physicians told her she had human epidermal growth factor receptor 2 (HER2) positive 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. It affects approximately 25 percent of women diagnosed with breast cancer.

"I was scared but I was determined to do everything I could to fight breast cancer," said Padgett. "I traveled out of state and eventually worked with a local doctor who convinced me to enroll in a clinical trial of the breast cancer drug Herceptin, which ended up being the right move for me."

Recently, 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 patients with 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.

HER2-positive breast cancer affects approximately 25 percent of women diagnosed with breast cancer. Research has shown that, compared to women with HER2-negative breast cancer, women with HER2-positive breast cancer have a greater likelihood of:

- recurrence
- poor prognosis
- decreased survival.

The addition of Herceptin to standard therapy significantly reduced the risk.

Herceptin is also approved for the treatment of HER2-positive metastatic breast cancer as a first-line therapy in combination with chemotherapy (paclitaxel) and as a monotherapy in patients who have received one or more chemotherapy regimens for their metastatic disease.

"The approval of Herceptin for early-stage HER2-positive breast cancer means that the prognosis for women with one of the most worrisome types of breast cancer could change," said Edward Romond, M.D., Professor of Medicine, Division of Hematology/Oncology at the University of Kentucky. "The results of the clinical trials which the approval is based upon represent the largest improvement in outcome for any group of women with breast cancer in 25 years."

The FDA approval of Herceptin was based on studies that showed the addition of Herceptin to standard therapy significantly reduced the risk of breast cancer from returning by 52 percent and may help some patients with HER2-positive breast cancer live longer.

Herceptin administration can result in left ventricular dysfunction and congestive heart failure. Serious infusion reactions and pulmonary toxicity have occurred; rarely, these have been fatal.

"Given the positive outcome in the Herceptin adjuvant trials, women should always receive a test to determine if their tumor is HER2-positive," said Dr. Romond. "This allows the physician to make the most informed decision about how to treat them."

For more information about Herceptin or HER2-positive breast cancer, women should talk to their doctor or visit www.herceptin.com.

For full prescribing information, including BOXED WARNINGS for Herceptin, please call (800) 821-8590 or visit www.gene.com.

HERCEPTIN SAFETY INFORMATION:

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 have these 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, rash, neutropenia, anemia, and myalgia.