

Hematology-Oncology Associates

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***** For Immediate Release *****

Patients of Hematology-Oncology Associates of CNY Participate in the Groundbreaking Study with Herceptin

Patients of Hematology-Oncology Associates of CNY were participants in the groundbreaking study of trastuzumab, also known as Herceptin. Results from two large randomized clinical trials for patients with HER-2 positive invasive breast cancer show that those patients with early stage breast cancer who received trastuzumab in combination with chemotherapy had a significant decrease in risk for breast cancer recurrence compared with patients who received the same chemotherapy without trastuzumab. Patients are considered “HER-2 positive” if their cancer cells “over express” or make too much of a protein found on the surface of cancer cells called HER-2. These tumors tend to grow faster and are generally more likely to recur than tumors that do not overproduce HER-2.

The National Cancer Institute (NCI) and part of the National Institutes of Health sponsored the clinical trials. The trials were 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. Genentech, Inc. manufactures trastuzumab and provided the drug for the trials.

Hematology-Oncology Associates, in their 18-year partnership with the NCI through their Clinical Community Oncology Program (CCOP) was able to join the network of researchers and allow their patients access to the clinical trial. The only other CCOP in New York State with access to this trial is on Long Island. “This was a wonderful celebration for our practice and our patients,” stated Maryann Roefaro, the cancer practice’s Chief Operating Officer. “This is one of

many examples that underscore the privileges we are allowed through our CCOP with the National Cancer Institute”.

The data monitoring committees overseeing the combined analysis of these trials recommended that the results of a recent interim analysis be made public because the studies met their primary endpoints of increasing disease-free survival in patients receiving Herceptin in combination with chemotherapy. Patients in the trials who received this chemotherapy regime demonstrated a 52 percent decrease in disease recurrence when compared with patients who received chemotherapy without Herceptin. This difference is highly statistically significant.

Edward Romond, MD, study chair for the NSABP and professor of oncology at the University of Kentucky noted, “For women with this type of aggressive breast cancer, the addition of trastuzumab to chemotherapy appears to virtually reverse prognosis from unfavorable to good. We owe a huge debt of gratitude to the women whose participation in these trials has made it possible to show the substantial benefit of combining trastuzumab with chemotherapy for adjuvant treatment of women with HER-2 positive breast cancer.”

Jeffrey J. Kirshner, MD, Medical Oncologist and Principle Investigator at Hematology-Oncology Associates of CNY stated, “We need to congratulate the women who chose to participate in this groundbreaking study. All too often when important trial results are announced, the focus is on the treatment and not the heroes who made the data possible.”

An estimated 211,240 women will be diagnosed with breast cancer in the US in 2005. Of these, about 30% will have lymph node positive breast cancer and about 20-30 percent of these tumors over express the HER-2 protein – the target for Herceptin. Breast cancer is the most commonly diagnosed cancer in women and is the second leading cause of cancer related death in women in our nation. An estimated 40,110 deaths from female breast cancer will occur in 2005 in the US, accounting for about 15 percent of all cancer related deaths in women.

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