VCU Massey Cancer Center physician-researcher Charles E. Geyer, Jr., M.D., was the National Protocol Officer for one component of a large national study involving two National Cancer Institute (NCI)-supported clinical trials that demonstrated that trastuzumab significantly improves the long-term survival of HER-2 positive breast cancer patients. The combined study was designed to determine the long-term safety and efficacy of the drug trastuzumab, which is commonly known as Herceptin and is primarily used alongside chemotherapy to treat HER2-positive breast cancer. The combined study focused on both the overall survival rates of patients up to ten years post-treatment as well as the known and potentially harmful side effects to the cardiac system.

Published in the *Journal of Clinical Oncology*, the study found that Herceptin, when added to chemotherapy, improved 10-year survival from 75 percent with chemotherapy alone to 84 percent with the addition of trastuzumab. Additionally, results also demonstrated continued improvement of survival without cancer recurrence—the 10-year disease-free survival rate increased from 62 percent to 74 percent with the addition of trastuzumab. Although heart problems are recognized side effects of Herceptin, the incidence rate of such events was found to be about 3 percent and the majority of those patients recovered from the initial effects.

"We have found that when Herceptin is used in combination with
chemotherapy, a patient's survival is significantly improved," said Geyer, who serves as a senior scientific advisor to the NSABP and at Massey is the Harrigan, Haw, Luck Families Chair in Cancer Research, associate director for clinical research and member of the Developmental Therapeutics research program, as well as professor in the Division of Hematology, Oncology and Palliative Care at the VCU School of Medicine. "There are minimal long-term side effects, and the likelihood of the cancer recurring is greatly reduced."

The study was designed to provide much needed long-term efficacy data on Herceptin—a proven effective treatment, but one without much information on the role it plays in patients' long-term survival. The study combines data from two trials: NSABP B-31, led by the National Surgical Adjuvant Breast and Bowel Project (NSABP), and NCCTG N9831, led by the North Central Cancer Treatment Group (NCCTG). Each trial was designed independently to analyze overall survival rates of patients with early-stage HER2-positive breast cancer. The study specifically addressed whether or not the patient experienced a cancer recurrence and if there were any harmful side effects that would diminish favorable treatment results.

The local principal investigator leading the NSABP B-31 trial at Massey was Harry Bear, M.D., Ph.D. Bear, who is the Dr. Walter Lawrence, Jr. Chair in Surgical Oncology, director of the Breast Health Center and medical director of the Clinical Trials Office at Massey, also serves on the Board of Directors of the NSABP Foundation, Inc.

Herceptin was approved by the Food and Drug Administration in 2006, based on the initial results of these two studies, as an adjuvant treatment for HER2-positive breast cancers, which test positive for the HER2 mutation and are often more aggressive than other types of breast cancers. HER2 - human epidermal growth factor receptor 2 - is a protein that plays a significant role in breast cancer. HER2 proteins are products
of the HER2 gene and work to control the growth of healthy cells. If the proteins are overexpressed, or if the HER2 gene is amplified, the cells can grow uncontrollably and become cancerous. Approximately 15 to 20 percent of invasive breast cancers result from HER2 gene amplification or overexpression of the HER2 protein.

Additional trials are currently underway to try to improve patient outcomes by using Herceptin in combination with various other drugs that also specifically target breast cancers with overexpressed HER2 proteins. Other trials are investigating applications of Herceptin for different cancers. For example, one study is presently investigating whether or not patients with breast cancers with lower amounts of HER2 protein might also benefit from Herceptin's promising results.

More information: jco.ascopubs.org/content/early ... 014.55.5730.full.pdf

Provided by Virginia Commonwealth University

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