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## **Clinical Trial at The Cancer Institute of New Jersey Focuses on New Treatment Combination for Most Common Type of Non-Invasive Breast Cancer**

*Drug Coupled with Breast Conserving Surgery and Radiation to Measure Effects Against Recurrence*

**New Brunswick, N.J., May 13, 2009** – Researchers at The Cancer Institute of New Jersey (CINJ) have launched a clinical trial that targets a new treatment combination for the most common type of non-invasive breast cancer known as ductal carcinoma in situ (DCIS). CINJ is a Center of Excellence of UMDNJ-Robert Wood Johnson Medical School.

In DCIS, the cancer cells are inside the milk ducts of the breast but have not spread to surrounding breast tissue. According to the American Cancer Society, one in five new breast cancer cases in the United States is diagnosed as DCIS, and nearly all diagnosed at this early stage can be cured.

The trial, sponsored by the National Surgical Adjuvant Breast and Bowel Project (NSABP), will compare the effects of adding the drug trastuzumab to radiation therapy following breast sparing surgery (lumpectomy) in patients whose DCIS makes too much of the protein known as HER2 (positive). Too much of this protein can cause a normal cell to turn cancerous and make existing cancer cells grow faster. Trastuzumab is considered a targeted therapy against HER2-positive breast cancer. Early information shows the drug may also help radiation therapy work better in treating HER2-positive breast cancer, although investigators caution more research is needed in this area.

Trastuzumab has approval from the U.S. Food and Drug Administration (FDA) for the treatment of HER2-positive breast cancer together with chemotherapy, but it is considered “investigational” in this trial, because its use in combination with radiation therapy has not been FDA approved. The primary aim of this study is to see if this new combination is more effective in preventing occurrence of DCIS in the same breast or in other parts of the body, versus giving radiation by itself following lumpectomy.

Antoinette R. Tan, MD, a medical oncologist at CINJ and assistant professor of medicine at UMDNJ-Robert Wood Johnson Medical School, is the lead investigator of the study at CINJ. “A previous study by the NSABP shows an overall recurrence rate of eight percent in this population 12 years following breast conserving surgery and radiation. If we can add another element to the standard treatment, we could possibly reduce that rate even further,” she said. The study is seeking 2,000 participants at multiple cancer centers across the country.

Before taking part in the trial, interested participants will undergo a physical exam and a mammogram. Of those selected, one group will receive radiation therapy for three to six weeks as part of their regular treatment following surgery, while the other group will receive both radiation treatment and trastuzumab, which will be given through injection. Following treatment, participants will have follow-up physical exams and a mammogram each year for the next ten years.

Women over age 18 who have been diagnosed with HER2-positive DCIS and have had a lumpectomy are eligible to participate, although other criteria also must be met. For more information on how to take part, individuals should call CINJ’s Office of Human Research Services at 732-235-8675.

Clinical trials, often called cancer research studies, test new treatments and new ways of using existing treatments for cancer. At CINJ, researchers use these studies to answer questions about how a treatment affects the human body and to make sure it is safe and effective. There are several types of clinical trials currently underway at CINJ, including those that diagnose, treat, prevent, and manage symptoms of cancer. Many treatments used today, whether drugs or vaccines; ways to do surgery or give radiation therapy; or combinations of treatments, are the results of past clinical trials.

As New Jersey's only National Cancer Institute-designated Comprehensive Cancer Center, CINJ offers patients access to treatment options not available at other institutions within the state. CINJ currently enrolls more than 1,000 patients on clinical trials, including approximately 15 percent of all new adult cancer patients and approximately 70 percent of all pediatric cancer patients. Enrollment in these studies nationwide is fewer than five percent of all adult cancer patients.

### **About The Cancer Institute of New Jersey**

The Cancer Institute of New Jersey ([www.cinj.org](http://www.cinj.org)) is the state's first and only National Cancer Institute-designated Comprehensive Cancer Center, and is dedicated to improving the prevention, detection, treatment and care of patients with cancer. CINJ's physician-scientists engage in translational research, transforming their laboratory discoveries into clinical practice, quite literally bringing research to life. The Cancer Institute of New Jersey is a center of excellence of UMDNJ-Robert Wood Johnson Medical School. To support CINJ, please call the Cancer Institute of New Jersey Foundation at 1-888-333-CINJ.

The Cancer Institute of New Jersey Network is comprised of hospitals throughout the state and provides a mechanism to rapidly disseminate important discoveries into the community. Flagship Hospital: Robert Wood Johnson University Hospital. Major Clinical Research Affiliate Hospitals: Carol G. Simon Cancer Center at Morristown Memorial Hospital, Carol G. Simon Cancer Center at Overlook Hospital, and Jersey Shore University Medical Center. Affiliate Hospitals: Bayshore Community Hospital, CentraState Healthcare System, Cooper University Hospital\*, JFK Medical Center, Raritan Bay Medical Center, Robert Wood Johnson University Hospital at Hamilton (CINJ at Hamilton), Saint Peter's University Hospital, Somerset Medical Center, Southern Ocean County Hospital, The University Hospital/UMDNJ-New Jersey Medical School\*, and University Medical Center at Princeton. \*Academic Affiliate

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