

DOCETAXEL IMPROVES SURVIVAL AND REDUCES RISK OF RELAPSE IN WOMEN WITH NODE-POSITIVE EARLY-STAGE BREAST CANCER

ASCO Abstract # 141: The first results of docetaxel as an adjuvant treatment show a large early benefit over a standard chemotherapy

ORLANDO, FL (May 19, 2002) – Women with early-stage breast cancer treated with a docetaxel-based regimen after surgery had 32 percent less chance of their cancer returning than women receiving one of the most effective adjuvant – or post-surgery – treatments available. Results from BCIRG 001, the first phase III study evaluating docetaxel after breast surgery, were presented at the American Society of Clinical Oncology (ASCO) meeting by the Breast Cancer International Research Group (BCIRG) today.

In the analysis of the study, women were divided into two groups, those with one to three positive lymph nodes and those with four or more. The most significant benefit from the use of docetaxel was seen in women with one to three positive lymph nodes. Among these women, treatment with docetaxel reduced the risk of relapse by 50 percent and reduced the mortality rate by 54 percent. Women with one to three positive lymph nodes make up 60 to 70 percent of all women worldwide with node-positive early-stage breast cancer.

“The superior results observed with the docetaxel-based regimen indicate that it can potentially cure more women than one of the best chemotherapies we have,” said Jean-Marc Nabholz, MD, chairman of the Breast Cancer International Research Group (BCIRG), study chairman, and Professor of Medicine at the University of California at Los Angeles and Director of the Cancer Therapy Development Program at the Jonsson Comprehensive Cancer Center at UCLA. “Although early, these results should be considered when choosing therapy for a large number of women with early breast cancer.”

The BCIRG 001 study was designed to determine if docetaxel, one of the most active agents in advanced breast cancer, would also have benefits for women with early-stage disease. Study participants received either a post-surgery regimen of docetaxel (Taxotere), doxorubicin (Adriamycin), and cyclophosphamide (Cytoxan), known as TAC, or the widely used standard regimen of 5-fluorouracil, doxorubicin and cyclophosphamide, known as FAC. BCIRG 001 enrolled 1,491

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women with early breast cancer at 111 sites in 20 countries. A total of 745 patients were randomized to receive TAC and 746 to receive FAC.

Nearly three years after treatment, the study results show that 82 percent of patients on TAC and 74 percent on FAC were alive and disease-free. For those treated with TAC, this represents a significant improvement in disease-free survival and a 32 percent reduction in the risk of recurrence ($p=0.0011$) when compared to those treated with FAC. Additionally, women treated with TAC had a nearly 50 percent less chance of their cancer returning and spreading throughout their body (metastatic relapse.)

Fifty-four percent of study participants were younger than 50 years of

age, 56 percent were premenopausal, 62 percent had one to three cancerous lymph nodes, 69 percent were hormone-receptor-positive, 60 percent had tumors larger than two centimeters and 20 percent had HER2-positive tumors. The benefit from TAC was observed regardless of hormone receptor status and HER2 receptor status.

“While still early, the results of this study are promising for reducing recurrence of breast cancer among early-stage patients,” said Susan Braun, president and chief executive officer of the Susan G. Komen Breast Cancer Foundation. “Perhaps more importantly, though, they highlight the importance of patient participation in clinical research trials and the extraordinary potential of global cooperation of breast cancer researchers to identify new and more effective treatments. The Komen Foundation strongly supports educating patients and physicians about the scientific benefits, as well as the high quality of patient care, associated with well-designed clinical trials.”

The study compared an equal number of treatment cycles for both treatment groups and more than 90 percent of patients in both treatment groups received all six cycles of treatment. The TAC regimen was associated with a higher incidence of febrile neutropenia (a fever that occurs at the time when white blood cells are decreased) compared with FAC (24 percent vs. 2 percent). However, no patients in either treatment group died of an infection due to treatment. The incidence of febrile neutropenia can be greatly reduced by GCSF (granulocyte colony-stimulating factor), a treatment widely used in clinical practice, but not required in this study.

Severe (Grade 3 or 4) infections occurred rarely with both treatments