



For more information:  
Emmanuelle Mekercke  
BCIRG Communication Manager  
(+) 331 58 10 08 97  
Emmanuelle.Mekercke@CIRG.ORG

For international media  
Alexandra Benarous  
GCI  
212 537 8297 (o)  
646 298 0363 (on site)

For US Media  
Jo Moseley  
Cohn & Wolfe  
212 798 9736 (o)  
347 645 4793 (on site)

**Embargoed for release until December 5<sup>th</sup>, 7:00 pm, CST**

**MAJOR ADVANCE IN CHEMOTHERAPY FOR WOMEN  
WITH NODE POSITIVE EARLY BREAST CANCER**

**Docetaxel (Taxotere<sup>®</sup>)-based regimen (TAC) improves survival and disease free survival:  
analysis at 55-month follow-up**

*San Antonio Breast Cancer Symposium - Abstract # 43*

San Antonio, TX – December 5, 2003 – A Docetaxel (Taxotere<sup>®</sup>)-based regimen reduced the relative risk of death in women with early stage breast cancer by 30 percent and lowered the relative risk of the cancer returning by 28 percent when compared to a standard adjuvant (post-surgery) regimen after 55-month follow-up. The results of BCIRG 001, the first phase III study evaluating Taxotere after breast surgery, were presented at the San Antonio Breast Cancer Symposium (SABCS) by the Breast Cancer International Research Group (BCIRG) today.

“Taxotere continues to demonstrate its effectiveness across various stages of breast cancer, and this study indicates that women with early stage breast cancer and their physicians should seriously consider a Taxotere-based treatment, like the TAC regimen tested in the BCIRG 001 trial, to significantly prolong disease-free survival and survival,” said Miguel Martin M.D. from the Medical Oncology Department, Hospital Universitario San Carlos, Madrid, Spain, chairman of GEICAM.

## **Study Design**

The BCIRG 001 study was designed to determine if Taxotere, 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 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 pre- and post-menopausal women with early breast cancer at 111 sites in 20 countries; 745 patients were randomized to receive TAC and 746 to receive FAC. The study was designed to perform analyses on subgroups of women based on hormonal receptor status (hormone-receptor-positive or hormone-receptor-negative tumors) and nodal involvement (one-to-three or four-plus axillary lymph nodes). Tumor samples were prospectively collected for 95 percent of the patients. Hormonal receptor status, Her2neu amplification (FISH) as well as other tumor characteristics were centrally reviewed by an independent pathologist.

## **Study Results**

At five years follow-up, 75 percent of patients on TAC and 68 percent of patients on FAC were disease-free. This corresponds to a 28 percent reduction in the relative risk of recurrence ( $p=0.0010$ ). This also resulted in a survival advantage for patients treated with TAC. Eighty-seven percent of patients on TAC and 81 percent of patients on FAC were alive, which represents a 30 percent reduction in relative risk of mortality ( $p=0.0080$ ) in favor of TAC patients. The significant benefits in favor of the Taxotere arm were observed in both hormone-receptor-positive (HR+) and hormone-receptor-negative (HR-) patients, with a reduction in the recurrence of disease of 27 percent and 34 percent respectively. A significant disease-free survival benefit was also observed independent of Her2neu expression.

“These robust and mature results indicate that Taxotere in combination with doxorubicin and cyclophosphamide help women live longer and reduce the risk of cancer relapse,” said John R. Mackey, M.D., FRCP(C), Department of Oncology, University of Alberta, and Cross Cancer Institute, Edmonton, Canada. “After almost five years of follow-up, we are confident that this Taxotere-based treatment can cure more women than one of the standard chemotherapy regimens we currently use”

"This study confirms that Taxotere is a very compelling component of future combinations being developed for the treatment of early stage breast cancer with new therapies coming from biological research," stated Dennis J. Slamon, M.D., Ph.D. Chief, Division of Hematology-Oncology; UCLA School of Medicine, Los Angeles.

Both regimens were administered with high compliance, as 97 percent patients on FAC and 91 percent patients on TAC received the planned six cycles of chemotherapy.

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 patients receiving FAC, but this did not result in significantly different or elevated rates of moderate to severe infections in patients who received TAC compared with FAC. There were no toxic deaths and no long-lasting toxicities with either treatment arm.

"These results offer a promising new treatment option for reducing the risk of recurrence and mortality of early breast cancer patients," said Susan Braun, president and chief executive officer of the Susan G. Komen Breast Cancer Foundation. "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."

"BCIRG 001 is the first large adjuvant trial conducted by the Breast Cancer International Research Group. The TAC regimen constitutes the standard regimen for other trials with taxanes carried out by national and international cooperative groups," stated Charles Vogel, M.D., from the Cancer Research Network in Plantation, Florida.

### **About Breast Cancer**

Breast cancer is an abnormal cell growth originating in breast tissue. If not diagnosed and treated early, these cells can invade surrounding tissue and spread through the blood and lymph node system.

An estimated 211,300 women in the U.S. will be diagnosed with breast cancer this year, and an estimated 40,000 women will die from the disease. Worldwide, almost 1 million women are diagnosed with this disease each year. In the United States and Europe, it is the most

common cancer among women, excluding skin cancer, and the second leading cause of cancer death among women.

### **About BCIRG**

BCIRG is an academic global cooperative intergroup of oncology researchers dedicated to the global strategic development of promising new therapies for women with breast cancer. The goal of BCIRG is to identify and select the best compounds in their class (chemotherapy, hormone therapy, biologic modifiers and gene therapy) and to create global pivotal strategies of development in order to test these new treatments and bring them to patients in a timely manner. Academic rigor, speed, quality of processes and worldwide patient access are achieved through the interaction of the most advanced academic institutions in the world and a large global network of clinical investigators. BCIRG is a division of Cancer International Research Group, a not-for-profit organization.

The study was sponsored by Aventis. Aventis manufactures docetaxel under the trade name Taxotere<sup>®</sup>.

###