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**BCIRG 001 STUDY HAS BEEN ACCEPTED BY THE U.S FDA TO APPROVE  
DOCETAXEL (TAXOTERE) IN COMBINATION WITH DOXORUBICIN AND  
CYCLOPHOSPHAMIDE (TAC) FOR THE ADJUVANT TREATMENT OF WOMEN  
WITH NODE-POSITIVE EARLY-STAGE BREAST CANCER**

*-- Docetaxel (Taxotere®)-in combination with doxorubicin and cyclophosphamide (TAC)  
Approved for Treatment of Women with Node-Positive Early-Stage Breast Cancer --*

**EDMONTON, CANADA – August 19, 2004** – The U.S. Food and Drug Administration (FDA) has approved the use of the docetaxel-based regimen, TAC, for the treatment of patients with operable, node-positive breast cancer. The FDA based its decision on data from a pivotal study conducted by the Breast Cancer International Research Group (BCIRG).

The study, known as BCIRG 001, demonstrates that women with node-positive, early-stage breast cancer who received TAC (docetaxel with doxorubicin and cyclophosphamide) after surgery experienced a 25.7 percent reduction in their risk of relapse (the chance of their cancer returning) as compared to women treated with a standard adjuvant regimen known as FAC (5-fluorouracil, doxorubicin and cyclophosphamide).

“Taxotere® continues to demonstrate its effectiveness across various stages of breast cancer, and the FDA’s decision may set the TAC regimen as a leading choice in the treatment of women with node-positive, early-stage breast cancer,” said Miguel Martin MD, CoChair of the BCIRG 001 study, Medical Oncology Department, Hospital Universitario San Carlos, Madrid, Spain, and Chairman of GEICAM. “The benefit of the

Taxotere regimen was observed regardless of the number of positive lymph nodes or hormone receptor status.”

“Data from the BCIRG study suggest that by adding docetaxel to a standard chemotherapy regimen after surgery, we now have a treatment option that offers women with early-stage breast cancer a greater chance of disease-free survival,” said Dennis Slamon, PhD MD, Chair of the BCIRG Scientific Committee Director of Clinical and Translational Research at UCLA’s Jonsson Comprehensive Cancer Center.

### **About the BCIRG 001 Study**

The BCIRG 001 study was designed to determine if docetaxel (Taxotere<sup>®</sup>), one of the most active agents in advanced breast cancer, would benefit women with early stage disease. After surgery, study participants received either TAC (Taxotere<sup>®</sup> together with doxorubicin and cyclophosphamide) or the standard regimen of FAC (5-fluorouracil, doxorubicin and cyclophosphamide). 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 allow for prospective analyses on subgroups of women based on hormonal receptor status (hormone-receptor-positive or hormone-receptor-negative tumors) and nodal involvement (1-3 or 4+ positive axillary lymph nodes).

### **Study Results**

The BCIRG 001 study demonstrated that women with node-positive, early stage breast cancer who received TAC after surgery experienced a significant 25.7 percent reduction (hazard ratio=0.74, 2-sided 95% CI= 0.6, 0.92, stratified log rank p=0.0047) in their risk of relapse (or the chance of their cancer returning) as compared to women treated with another adjuvant combination regimen of 5-fluorouracil, doxorubicin, and cyclophosphamide (FAC). With 55 months follow-up, the significant reduction in the risk of relapse with TAC was observed regardless of a woman’s hormone receptor status or nodal status.

At the time of this second planned interim analysis, based on 219 deaths, overall survival was longer for TAC than FAC (hazard ratio=0.69, 2-sided 95% CI=0.53, 0.90). There will be a further analysis at the time survival data mature.

““BCIRG 001 is the first adjuvant trial conducted by the Breast Cancer International Group, and the strength of our data will support a shift from prior standards of care to this Taxotere-based regimen” said John R. Mackey, MD, FRCP(C), CoChair of the study, Department of Oncology, University of Alberta, and Cross Cancer Institute, Edmonton, Canada.

“This was a well-conducted trial; the data is robust and indicate that the TAC regimen is an advance for patients with node positive breast cancer”, says Dr. Charles Vogel, MD, FACP, P.A. CoChair of the study, Cancer Research Network, Plantation, Florida.

More than 90 percent of patients in both 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 low which in turn can lead to infections) compared to that seen in patients receiving FAC. However, this did not result in significantly different or elevated rates of severe infections in patients who received TAC compared with FAC. There were no treatment-related deaths due to infection in the study.

Other severe toxicities noted in 5% or more of the patients treated with TAC included neutropenia, nausea, stomatitis and asthenia, and with FAC, neutropenia, nausea, vomiting and asthenia, respectively.

### **Breast Cancer**

Breast cancer is the most common cancer among women other than skin cancer. It is the second-leading cause of cancer death in women after lung cancer -- and is the leading cause of cancer death among women ages 40 to 59. More than 1,000,000 new cases of breast cancer are reported worldwide annually and more than 400,000 women die each year from the disease.

### **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. Its academic rigor, speed, high quality 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.

## **Acknowledgments**

BCIRG wishes to thank the patients who accepted to be a part of this pivotal registration study; and the investigators and their research teams for their dedication to the BCIRG 001 clinical trial.

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

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