



### **BCIRG 001 Study in Early Breast Cancer**

Published in the *New England Journal of Medicine*

Edmonton, AB, Canada – Paris, France – 02, June 2005 – Breast Cancer International Research Group (BCIRG) is proud to announce the publication of its pivotal study BCIRG 001: Adjuvant docetaxel for node-positive breast cancer in the *New England Journal of Medicine*, 352 (vol. 22) p. 2304-2313 June 2, 2005.

This international phase III study randomized 1,491 patients in 20 countries to compare docetaxel (Taxotere®) in combination with doxorubicin / cyclophosphamide (TAC) chemotherapy with 5-fluorouracil / doxorubicin / cyclophosphamide (FAC) in adjuvant treatment of patients with positive axillary lymph nodes. Completed one year ahead of schedule, the speed and high-quality of this BCIRG study defined the superiority of Taxotere in anthracycline-based combinations in the adjuvant treatment of breast cancer. The BCIRG 001 study led to a successful Federal Drug Administration approval to register Taxotere in the US in August 2004 and subsequently in Europe few weeks later.

The success of this study is a testament to the concept of an Academic Global Cooperative Group upon which BCIRG is based. Using academic investigators around the world, BCIRG is pursuing its focus on the pivotal development of new cancer therapies, including chemotherapy, hormonal, and biologic targeted treatments. To further accelerate progress in cancer therapy, BCIRG recently partnered with Translational Oncology Research International (TORI) to take advantage of the growing molecular understanding of the fundamental biologic problems underlying cancer. TORI, founded by Dr. D. Slamon, Head of the Division of Hematology/Oncology at David Geffen School of Medicine at UCLA, has been instrumental in bringing new biologic anticancer drugs from the laboratory and introducing them into clinical trials.

In a convincing demonstration of the power of biologic anticancer drugs, trastuzumab (humanized anti-body HER2 modifier) has improved disease free and overall survival in early stage breast cancer. The BCIRG 006 trial studied 3,222 women with early stage breast cancer to exploit the synergy between chemotherapy and trastuzumab. Our early results confirm the safety of this approach, and efficacy data from this trial is eagerly awaited by the medical community. With results expected within a few months, the

BCIRG 006 is poised to establish a new standard for the adjuvant treatment of women with HER-2 driven breast cancer.

### **About Us**

BCIRG is the scientific division of the non-for-profit CIRG (Cancer International Research Group) an Academic Research Organization led by internationally recognized cancer researchers. A strong clinical operations division provides a complete range of services to conduct and management of its clinical trials, ranging from small proof of concept studies up to international phase III trials. CIRG is located in Paris (France) and Edmonton AB (Canada).

For information about CIRG/BCIRG, please visit our website: [WWW.CIRG.ORG](http://WWW.CIRG.ORG)

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