



PRESS RELEASE

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ALTTO Test of Dual HER2 Blockade Finds Single Agent - Trastuzumab - Remains the Gold Standard

Brussels, Belgium – In the largest clinical trial testing the effectiveness of one versus two drugs to treat HER2-positive breast cancer, lapatinib (Tykerb®) did not add benefit to the standard trastuzumab (Herceptin®) adjuvant therapy, researchers reported at the 50th annual meeting of the American Society of Clinical Oncology (ASCO) in Chicago, IL, USA.

Results of the phase III clinical trial, ALTTO (Adjuvant Lapatinib and/or Trastuzumab Treatment Optimization study), demonstrated that adding lapatinib to trastuzumab did not improve disease-free survival or overall survival, and that use of lapatinib significantly increased toxicity.

Findings suggest that standard treatment for early stage HER2-positive breast cancer should remain trastuzumab in combination with chemotherapy.

The ALTTO trial did not meet its primary endpoint, which was a significant increase in disease free survival comparing trastuzumab to the combination of trastuzumab plus lapatinib. Also, there was no improvement when comparing single agent trastuzumab versus a regimen of trastuzumab followed by lapatinib.

In addition, ALTTO findings did not confirm the benefit of using both anti-HER2 therapies predicted from the NeoALTTO clinical trial, which tested the therapies before cancer surgery.

The 8,381 participants, 42 country phase III clinical trial is a collaboration between the Breast International Group (BIG) and the Breast Cancer Intergroup of North America (TBCI), and is

supported by the US National Cancer Institute (part of the US National Institutes of Health) and GlaxoSmithKline, maker of lapatinib.

Dr Martine Piccart, BIG Chair and Head of Medicine at the Institut Jules Bordet, and Dr Edith Perez, Deputy Director at Large of the Mayo Clinic Cancer Center, and Director of the Breast Cancer Translational Genomics Program at Mayo Clinic in Florida, are co-principal investigators of ALTTO. Dr Piccart presented results of NeoALTTO at the 2013 San Antonio Breast Cancer Symposium.

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About ALTTO

The Adjuvant Lapatinib and/or Trastuzumab Treatment Optimisation (ALTTO) trial is a randomised, phase III trial comparing one year of anti-HER2 therapy with lapatinib alone (L), trastuzumab alone (T), their sequence (T→L) or their combination (T+L) in the adjuvant treatment of HER2-positive early breast cancer. The sponsors are GlaxoSmithKline and the National Cancer Institute (in US).

From Jan 2007 to Jul 2011, 8,381 patients were randomized from 946 participating sites in 44 countries to receive either T alone (N=2097), L alone (N=2100), T→L (N=2091), or T+L (N=2093). Anti-HER2 therapy was initiated after completion of all chemotherapy (Design 1), concomitantly with a taxane following anthracycline (Design 2), or concomitantly with a non-anthracycline, platinum-containing regimen (Design 2B).

About Breast International Group (BIG)

The Breast International Group (BIG) is a non-profit organisation for academic breast cancer research groups from around the world, with its headquarters in Brussels, Belgium. Founded by leading European opinion leaders in 1999, BIG now constitutes a network of 49 collaborative groups based in Europe, Canada, Latin America, Asia and Australasia. These entities are tied to several thousand specialised hospitals and research centres worldwide. About 30 clinical trials are run or are under development under the BIG umbrella at any one time. BIG also works closely with the US National Cancer Institute (NCI) and the North American Breast Cancer Group (NABCG), so that together they act as a strong integrating force in the breast cancer research arena.

BIG facilitates and accelerates international breast cancer research by stimulating cooperation between its members and other academic networks, and collaborating with, but working independently from, the pharmaceutical industry. Large-scale cooperation is crucial to make significant advances in breast cancer research, reduce unnecessary duplication of effort, and optimally serve those affected by the disease.

www.BIGagainstbreastcancer.org

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