

## Abstract

# BCIRG 006: Docetaxel and trastuzumab-based regimens improve DFS and OS over AC-T in node positive and high risk node negative HER2 positive early breast cancer patients: Quality of life (QOL) at 36 months follow-up

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**Background:** The primary objective of the BCIRG 006 trial was to determine if the use of trastuzumab in early high-risk HER2-positive breast cancer significantly improved clinical outcomes. A secondary objective was to evaluate the QOL of patients receiving the 2 treatments. **Methods:** The BCIRG 006 trial compared adjuvant standard AC (doxorubicin/cyclophosphamide x 4 cycles) followed by docetaxel x 4 [AC-T] or 2 trastuzumab-containing regimens, AC followed by T with trastuzumab x 1 year [AC-TH] or TCarbo x 6 with trastuzumab x 1 year [TCH] in patients with node positive or high-risk node negative HER2-positive early breast cancer (n=3222). **Results:** The 2nd planned interim analysis, median follow-up at 36 months, showed that both AC-TH and TCH significantly improved the DFS and OS over the control (relative reduction risk of relapse 39% ( $P<0.0001$ ) and 33% ( $P=0.0003$ ) respectively, for AC-TH and TCH vs control). Relative reduction in the risk of death was 41% ( $P=0.0041$ ) and 34% ( $P=0.017$ ) respectively, for AC-TH and TCH vs control. Congestive heart failure occurred in 0.4% of patients in AC-T and TCH vs 1.9% of patients in AC-TH. Global safety profile was acceptable in all 3 arms and more favourable in TCH than AC-TH. QOL, a secondary endpoint of this trial, was assessed using the EORTC QLQC-30, BR-23, and EQ5D. We will present the primary QOL endpoints comparing Physical Function, Global Health Status, Future Perspectives, and Systemic Treatment Effects change scores from baseline to mid-chemotherapy, end of chemotherapy, and 12 months follow-up (with a 10% change considered clinically important). The proportion of patients with improved/stable/worsened QOL scores will be compared with chi-square tests. Other QOL exploratory analyses will be presented.