



NEOALTTO IS THE NEOADJUVANT STUDY INVESTIGATING DUAL HER2 BLOCKADE IN EARLY BREAST CANCER WITH THE LONGEST CLINICAL FOLLOW-UP (ALMOST TEN YEARS)

NEOALTTO (BIG 1-06) BENEFIT OF DUAL HER2-TARGETED THERAPY

The first results of NeoALTTO, published in *The Lancet*¹ in 2012, showed a near doubling of the pathological complete response (pCR) – meaning a disappearance of all visible signs of cancer – in patients who received a combination of trastuzumab and lapatinib (two HER2-targeted agents) rather than the single agent alone (trastuzumab or lapatinib) before surgery.

The long-term analysis, presented in 2020 after following patients for about ten years, showed that women who achieved pCR have significantly higher survival rates (i.e., event free and overall survival rates) compared to those who did not. It confirmed that pCR is likely an indicator of long-term benefit of treatment in HER2-positive breast cancer. This trend is more important in patients whose disease is hormone receptor-negative and in the population receiving the combination of lapatinib and trastuzumab.

The analysis did not report any new or long-term safety concerns.

Developed in parallel with its sister trial ALTTO (BIG 2-06), the NeoALTTO study included 455 patients and was set up to investigate whether combining trastuzumab (Herceptin®) with another drug called lapatinib (Tykerb®) – given either alone, together or one after the other – could benefit patients with HER2-positive primary breast cancer in the neoadjuvant (pre-surgical) setting.

NeoALTTO is a study co-led by SOLTI Breast Cancer Group, BIG Headquarters, Institut Jules Bordet's Clinical Trials Support Unit (IJB-CTSU) and Frontier Science & Technology Research Foundation (FSTRF).

The study was sponsored and funded by GlaxoSmithKline (GSK) until 30 November 2015, after which these responsibilities were transferred to Novartis. The study was designed and conducted following BIG's academic research principles.

Reference:

¹ Baselga J, Bradbury I, Eidtmann H, et al. Lapatinib with trastuzumab for HER-positive early breast cancer (NeoALTTO): a randomised, open-label, multicentre, phase 3 trial. *Lancet* 2012 Feb 18;379(9816):633-40

"[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(11\)61847-3/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(11)61847-3/fulltext)"

NEOALTTO: THE STRENGTH OF INTERNATIONAL COLLABORATION

- > ALMOST 10 YEARS FOLLOW-UP OF PATIENTS
- > TOGETHER WITH ALTTO, MORE THAN 8,000 PATIENTS INVOLVED
- > A HUGE PROSPECTIVE COLLECTION OF SAMPLES FOR FUTURE RESEARCH PROJECTS
- > A TREMENDOUS INTERNATIONAL COLLABORATION BETWEEN PATIENTS, RESEARCHERS, DOCTORS AND NURSES AND PHARMA