**A randomized, double-blind, phase III study comparing SB3 (trastuzumab biosimilar) with originator trastuzumab in patients treated by neoadjuvant therapy for HER2-positive early breast cancer.**

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**Background:** SB3, a proposed biosimilar to the originator trastuzumab (TRZ), demonstrated similarity to its originator in terms of biological activities and pharmacokinetic (PK) equivalence. This study compared SB3 to TRZ in terms of efficacy, safety, PK, and immunogenicity in patients treated by neoadjuvant therapy for HER2 positive early breast cancer (NCT02149524). **Methods:** Phase III, randomized, double blind, multicenter study compared neoadjuvant SB3 or TRZ for 8 cycles concurrently given with chemotherapy (docetaxel followed by 5-fluorouracil/epirubicin/cyclophosphamide). Then patients underwent surgery followed by 10 cycles of SB3 or TRZ. The primary endpoint was breast pathologic complete response (bpCR) rate. Equivalence was declared if the 90% confidence interval (CI) of the ratio or the 95% CI of the difference of the bpCR rates in the per-protocol set (PPS) were contained within the pre-defined equivalence margins (0.785, 1.546) and (-13%, 13%), respectively. Secondary endpoints were total pathologic complete response (tpCR), overall response rate (ORR), event-free survival, PK, immunogenicity, and safety. **Results:** 800 patients were included in PPS. The bpCR rates were 51.7% for SB3 and 42.0% for TRZ. The ratio of bpCR rate was 1.259 and its 90% CI was 1.112-1.426, within the pre-defined equivalence margin. The difference of bpCR rate was 10.70% and its 95% CI was 4.13-17.26; the lower margin was contained within, the upper margin was outside the pre-defined equivalence margin. Secondary endpoints were comparable between SB3 vs TRZ: tpCR rate (45.8% vs 35.8%); ORR (96.3% vs 91.2%). Safety was comparable between SB3 vs TRZ during neoadjuvant period: incidence of treatment-emergent adverse events (96.6% vs 95.2%), most commonly neutropenia, alopecia, and nausea; incidence of serious adverse events (10.5% vs 10.7%). PK equivalence was demonstrated and immunogenicity between SB3 vs TRZ was comparable (0.7% vs 0.0%). **Conclusions:** Equivalence was demonstrated between SB3 and TRZ based on the ratio of bpCR rates. Safety, PK, and immunogenicity were similar. Complete safety and survival data will follow. [Clinical trial information: NCT02149524.](http://clinicaltrials.gov/show/NCT02149524%22%20%5Ct%20%22_blank)