

Roche, GlaxoSmithKline - ALTTO trial- Tykerb alone arm discontinuation- Read-through for Head to Head Study vs. Herceptin in First line HER2+ve Breast Cancer setting

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Abstracts

Based on a planned interim review of early data from ALTTO (Adjuvant lapatinib and/or Trastuzumab Treatment Optimization trial), a Phase III, four arm study of adjuvant lapatinib (Tykerb), trastuzumab, their sequence and their combination in patients with HER2 positive early stage breast cancer, GSK announced that the Data Safety Monitoring Board (DSMB) has indicated that Tykerb alone arm is unlikely to meet the prespecified criteria to demonstrate non-inferiority to Herceptin alone with respect to disease free survival and hence has recommended patients assigned to Tykerb alone arm of the trial should discontinue. While DSMB has asked patients on the rest of three arms (Herceptin alone, Herceptin/Lapatinib as combination and sequential therapy) should continue on their respective therapies.

Contents

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