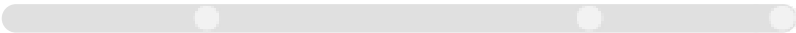




PRELIMINARY SCORE

CURATIVE



NON-CURATIVE



ADJUSTMENTS

Quality of life



Serious and disabling adverse effects

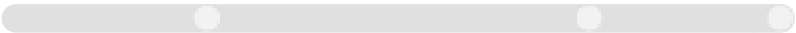


Other adjustments



SCORE

CURATIVE



Overall Survival / Disease-Free Survival / Pathological Complete Response

NON-CURATIVE



Overall Survival



Progression-Free Survival



Non-inferiority (Improved Quality of Life or Reduced Adverse Events) / Response Rate



Overall Response Rate / Duration of Response

Overall Survival / Disease-Free Survival / Pathological Complete Response

INFORMATION

Therapeutic Indication: EMA: Trastuzumab deruxtecan as monotherapy is indicated for the treatment of adult patients with unresectable or metastatic hormone receptor (HR)-positive, HER2-low or HER2-ultralow breast cancer who have received at least one endocrine therapy in the metastatic setting and who are not considered suitable for endocrine therapy as the next line of treatment. FDA: Trastuzumab deruxtecan for unresectable or metastatic hormone receptor (HR)-positive, HER2-low (IHC 1+ or IHC 2+/ISH-) or HER2-ultralow (IHC 0 with membrane staining) breast cancer, that has progressed on one or more endocrine therapies in the metastatic setting. Experimental Arm: Trastuzumab deruxtecan Control Arm: Investigator's choice chemotherapy (Capecitabine, Paclitaxel, Nab-Paclitaxel)



