PRELIMINARY SCORE

CURATIVE

NON-CURATIVE

PFS

ADJUSTMENTS

Quality of life

?

QoL data pending

Serious and disabling adverse effects

Other adjustments

Datopotamab deruxtecan TROPION-Breast01

SCORE

CURATIVE

Overall Survival / Disease-Free Survival / Pathological Complete Response

NON-CURATIVE

Overall Survival

3

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: Datopotamab deruxtecan as monotherapy is indicated for the treatment of adult patients with unresectable or metastatic hormone receptor (HR)-positive, HER2-negative breast cancer who have received endocrine therapy and at least one line of chemotherapy in the advanced setting. FDA: Datopotamab deruxtecan for the treatment of adult patients with unresectable or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC1+ or IHC2+/ISH-) breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease.
Experimental Arm: Datopotamab deruxtecan
Control Arm: Investigator’s choice of chemotherapy (Eribulin, capecitabine, vinorelbine, or gemcitabine)