Sacituzumab govitecan

TROPiCS-02

Sacituzumab govitecan TROPiCS-02

PRELIMINARY SCORE

CURATIVE

NON-CURATIVE

OS

ADJUSTMENTS

Quality of life

Delayed deterioration claimed, does not meet ESMO-MCBS QoL standards

Serious and disabling adverse effects

Other adjustments

Sacituzumab govitecan TROPiCS-02

SCORE

CURATIVE

Overall Survival / Disease-Free Survival / Pathological Complete Response

NON-CURATIVE

4

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: Treatment of adult patients with unresectable or metastatic hormone receptor (HR)-positive, HER2-negative breast cancer who have received endocrine-based therapy, and at least two additional systemic therapies in the advanced setting
Experimental Arm: Sacituzumab govitecan
Control Arm: Physician's choice chemotherapy (eribulin, vinorelbine, capecitabine, or gemcitabine)