

Repotrectinib

TRIDENT-1

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

Tumour type: Thoracic Malignancies

Therapeutic Indication: FDA: Repotrectinib used for locally advanced or metastatic ROS1-positive non-small cell lung cancer. FDA approval that includes patients with ROS1-positive NSCLC who have previously received a ROS1 tyrosine kinase inhibitor (TKI). EMA: Repotrectinib as monotherapy is indicated for the treatment of adult patients with ROS1-positive advanced non-small cell lung cancer (NSCLC) who have previously received a ROS1 tyrosine kinase inhibitor (TKI).

Experimental Arm: Repotrectinib

Control Arm: Single arm

