

Entrectinib STARTRK-1; STARTRK-2; ALKA-372-001

PRELIMINARY SCORE

CURATIVE



NON-CURATIVE



ADJUSTMENTS

Quality of life



Serious and disabling adverse effects



Other adjustments



Entrectinib STARTRK-1; STARTRK-2; ALKA-372-001

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: Tumour agnostic
 Therapeutic Indication: Treatment of adult and paediatric patients older than 1 month with solid tumours that have NTRK gene fusion, who have disease that is locally advanced, metastatic or where surgical resection is likely to result in severe morbidity, and who have not received a prior NTRK inhibitor, and who have no satisfactory treatment options.
 Experimental Arm: Entrectinib
 Control Arm: Single arm trials (Phase I/II)



