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

PRELIMINARY SCORE

CURATIVE

NON-CURATIVE

ORR

ADJUSTMENTS

Quality of life

Serious and disabling adverse effects

Other adjustments

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

FINAL 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

3

Overall Response Rate / Duration of Response

Overall Survival / Disease-Free Survival / Pathological Complete Response

INFORMATION

Tumour type: Refractory NTRK fusion-positive cancers
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)