

Selpercatinib LIBRETTO-001

PRELIMINARY SCORE

CURATIVE



NON-CURATIVE



ADJUSTMENTS

Quality of life



Serious and disabling adverse effects



Other adjustments



Selpercatinib LIBRETTO-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



Overall Response Rate / Duration of Response

Overall Survival / Disease-Free Survival / Pathological Complete Response

INFORMATION

Therapeutic Indication: EMA/FDA: Treatment for adult patients with locally advanced or metastatic solid tumors with a rearranged during transfection (RET) gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options (other than non-small cell lung cancer and thyroid cancer).

Experimental Arm: Selpercatinib

Control Arm: Single arm (Phase I/II)



