

Durvalumab TOPAZ-1

PRELIMINARY SCORE

CURATIVE



NON-CURATIVE



ADJUSTMENTS

Quality of life



Serious and disabling adverse effects



Other adjustments



Durvalumab TOPAZ-1

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: Gastrointestinal Cancers

Therapeutic Indication: Durvalumab in combination with gemcitabine and cisplatin is indicated for the first line treatment of adults with unresectable or metastatic biliary tract cancer

Experimental Arm: Durvalumab + Gemcitabine and cisplatin

Control Arm: Placebo + gemcitabine and cisplatin



