

Durvalumab TOPAZ-1

PRELIMINARY SCORE

CURATIVE

NON-CURATIVE

ADJUSTMENTS

Quality of life

No QoL benefit

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



