

Pembrolizumab KEYNOTE-966

PRELIMINARY SCORE

CURATIVE



NON-CURATIVE

OS



ADJUSTMENTS

Quality of life



exploratory endpoint



Serious and disabling adverse effects



Other adjustments



Pembrolizumab KEYNOTE-966

FINAL SCORE

CURATIVE



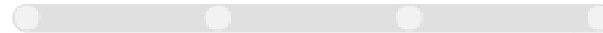
Overall Survival / Disease-Free Survival / Pathological Complete Response

NON-CURATIVE

1



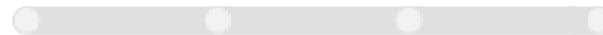
Overall Survival



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: EMA: Pembrolizumab in combination with gemcitabine and cisplatin, is indicated for the first-line treatment of locally advanced unresectable or metastatic biliary tract carcinoma in adults. FDA: Pembrolizumab to be used with gemcitabine and cisplatin for locally advanced unresectable or metastatic biliary tract cancer.

Experimental Arm: Pembrolizumab + Gemcitabine and cisplatin

Control Arm: Placebo + gemcitabine and cisplatin



