

PRELIMINARY SCORE

CURATIVE



NON-CURATIVE



ADJUSTMENTS

Quality of life



Not qualified for an ESMO-MCBS credit



Serious and disabling adverse effects



Other adjustments



SCORE

CURATIVE



Overall Survival / Disease-Free Survival / Pathological Complete Response

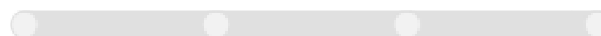
NON-CURATIVE



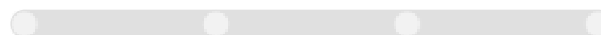
Overall Survival



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: EMA: Pembrolizumab for the first-line treatment of locally advanced unresectable or metastatic HER2-positive gastric or gastroesophageal junction adenocarcinoma in adults whose tumours express PD-L1 with a CPS ≥ 1 .

FDA: Pembrolizumab in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of patients with locally advanced unresectable or metastatic HER2 positive gastric or gastroesophageal junction (GEJ) adenocarcinoma whose tumors express PD-L1 (CPS ≥ 1).

Experimental Arm: Pembrolizumab + Trastuzumab, fluoropyrimidine + platinum-containing ChT

Control Arm: Placebo + trastuzumab, fluoropyrimidine + platinum-containing ChT



