

Nivolumab + ipilimumab

CheckMate 8HW

PRELIMINARY SCORE

CURATIVE



NON-CURATIVE



ADJUSTMENTS

Quality of life



Not qualified for an ESMO-MCBS credit



Serious and disabling adverse effects



Other adjustments



Long-term plateau in the PFS curve



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: Nivolumab in combination with ipilimumab is indicated for the treatment of adults patients with mismatch repair deficient or microsatellite instability-high in first-line treatment of unresectable or metastatic colorectal cancer. (Arm B + Arm C). FDA: Nivolumab with ipilimumab for adult and pediatric patients 12 years of age and older with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer (CRC).

Experimental Arm: Nivolumab + ipilimumab

Control Arm: Chemotherapy

