

Tremelimumab HIMALAYA

PRELIMINARY SCORE

CURATIVE



NON-CURATIVE



ADJUSTMENTS

Quality of life



Delayed deterioration in global QoL

Serious and disabling adverse effects



Other adjustments



Tremelimumab HIMALAYA

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: Treatment for adult patients in combination with durvalumab is indicated for the first line treatment of adults with advanced or unresectable hepatocellular carcinoma - FDA: Treatment for adult patients in combination with durvalumab with unresectable hepatocellular carcinoma

Experimental Arm: Tremelimumab + Durvalumab

Control Arm: Sorafenib



