

Trastuzumab ToGA

PRELIMINARY SCORE

CURATIVE



NON-CURATIVE



ADJUSTMENTS

Quality of life



Delay in deterioration did not meet MCBS
QoL criteria for upgrade.



Serious and disabling adverse effects



Other adjustments



Trastuzumab ToGA

FINAL 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: HER2-positive metastatic adenocarcinoma of the stomach or gastroesophageal junction in patients who have not received prior anti-cancer treatment for their metastatic disease

Experimental Arm: Trastuzumab + ChT (cisplatin + capecitabine or 5-FU)

Control Arm: ChT



