

Nanoliposomal irinotecan NAPOLI-1

PRELIMINARY SCORE

CURATIVE



NON-CURATIVE



ADJUSTMENTS

Quality of life



Serious and disabling adverse effects



Other adjustments



Nanoliposomal irinotecan NAPOLI-1

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: Treatment of metastatic adenocarcinoma of the pancreas, in combination with 5 fluorouracil (5 FU) and leucovorin (LV), in adult patients who have progressed following gemcitabine-based therapy
 Experimental Arm: Nanoliposomal irinotecan + 5-FU/LV
 Control Arm: 5-FU/LV



