

Irinotecan liposome NAPOLI 3

PRELIMINARY SCORE

CURATIVE



NON-CURATIVE



ADJUSTMENTS

Quality of life



Serious and disabling adverse effects



>20% increase in grade 3-4 toxicities
impacting daily life



Other adjustments



Irinotecan liposome NAPOLI 3

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: Irinotecan liposome with oxaliplatin, fluorouracil, and leucovorin, for the first-line treatment of metastatic pancreatic adenocarcinoma.

Experimental Arm: Irinotecan liposome + Oxaliplatin, fluorouracil, and leucovorin

Control Arm: Nab-paclitaxel + gemcitabine



