

Sunitinib A6181004

PRELIMINARY SCORE

CURATIVE



NON-CURATIVE



ADJUSTMENTS

Quality of life



QoL data pending



Serious and disabling adverse effects



Other adjustments



Early stopping based on OS advantage detected at interim analysis.



Sunitinib A6181004

SCORE

CURATIVE



Overall Survival / Disease-Free Survival / Pathological Complete Response

NON-CURATIVE



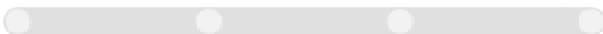
Overall Survival



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: Sarcoma

Therapeutic Indication: EMA: Sunitinib is indicated for the treatment of unresectable and/or metastatic malignant gastrointestinal stromal tumour (GIST) in adults after failure of imatinib treatment due to resistance or intolerance. FDA: Sunitinib for the treatment of patients with metastatic and/or unresectable GIST whose disease has progressed despite at least imatinib as prior treatments.

Experimental Arm: Sunitinib

Control Arm: Placebo



