

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.



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SCORE

CURATIVE



Overall Survival / Disease-Free Survival / Pathological Complete Response

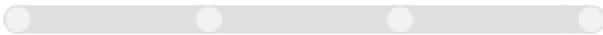
NON-CURATIVE



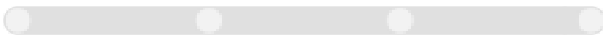
Overall Survival



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



