

PRELIMINARY SCORE

CURATIVE



NON-CURATIVE



ADJUSTMENTS

Quality of life



Serious and disabling adverse effects



Other adjustments



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: Afamitresgene autoleucl, a melanoma-associated antigen A4 (MAGE-A4)-directed genetically modified autologous T cell immunotherapy, for adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive and whose tumour expresses the MAGE-A4 antigen as determined by FDA-approved or cleared companion diagnostic devices

Experimental Arm: Afamitresgene autoleucl

Control Arm: Single arm

