Talimogene Laherparepvec OPTiM

PRELIMINARY SCORE

CURATIVE

NON-CURATIVE

OS

ADJUSTMENTS

Quality of life

Serious and disabling adverse effects

Other adjustments

Talimogene Laherparepvec OPTiM

SCORE

CURATIVE

Overall Survival / Disease-Free Survival / Pathological Complete Response

NON-CURATIVE

3

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: Skin Cancers
Therapeutic Indication: EMA: Indicated for the treatment of adults with unresectable melanoma that is regionally or distantly metastatic (Stage IIIB, IIIC and IVM1a) with no bone, brain, lung or other visceral disease. FDA: Indicated for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery.
Experimental Arm: Talimogene Laherparepvec
Control Arm: Subcutaneous granulocyte macrophage colony-stimulating factor (GM-CSF)