PRELIMINARY SCORE

CURATIVE

A

NON-CURATIVE

ADJUSTMENTS

Quality of life

Not qualified for an ESMO-MCBS credit

Serious and disabling adverse effects

Other adjustments

SCORE

CURATIVE

A

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: Thoracic Malignancies
Therapeutic Indication: EMA: Nivolumab, in combination with platinum-based chemotherapy as neoadjuvant treatment, followed by nivolumab as monotherapy as adjuvant treatment, is indicated for the treatment of resectable non-small cell lung cancer at high risk of recurrence in adult patients whose tumours have PD-L1 expression ≥ 1%. FDA: Nivolumab with platinum-doublet chemotherapy as neoadjuvant treatment, followed by single-agent nivolumab after surgery as adjuvant treatment, for adults with resectable (tumors ≥ 4 cm and/or node positive) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements.
Experimental Arm: Nivolumab + Platinum-doublet ChT
Control Arm: Placebo + platinum-doublet ChT