

Osimertinib

LAURA

PRELIMINARY SCORE

CURATIVE



NON-CURATIVE



ADJUSTMENTS

Quality of life



QoL data pending



Serious and disabling adverse effects



Other adjustments



Long-term plateau in the PFS curve



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: Thoracic Malignancies

Therapeutic Indication: FDA: Osimertinib for adult patients with locally advanced, unresectable (stage III) non-small cell lung cancer (NSCLC) whose disease has not progressed during or following concurrent or sequential platinum-based chemoradiation therapy and whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test. EMA: Osimertinib for adult patients with locally advanced, unresectable NSCLC whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations and whose disease has not progressed during or following platinum based chemoradiation therapy.

Experimental Arm: Osimertinib

Control Arm: Placebo



