

Ribociclib NATALEE

PRELIMINARY SCORE

CURATIVE



NON-CURATIVE



ADJUSTMENTS

Quality of life



Serious and disabling adverse effects



Other adjustments



Ribociclib NATALEE

SCORE

CURATIVE

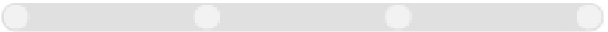


Overall Survival / Disease-Free Survival / Pathological Complete Response

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

Therapeutic Indication: EMA/FDA: Ribociclib with an aromatase inhibitor for the adjuvant treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer at high risk of recurrence. Additionally, FDA also approved the ribociclib and letrozole co-pack for the same indication.

Experimental Arm: Ribociclib + Non-steroidal aromatase inhibitor (NSAI)

Control Arm: Non-steroidal aromatase inhibitor (NSAI)



