Ribociclib

NATALEE

Ribociclib NATALEE

PRELIMINARY SCORE

CURATIVE

A

NON-CURATIVE

ADJUSTMENTS

Quality of life

QoL data pending

Serious and disabling adverse effects

Other adjustments

Ribociclib NATALEE

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

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)

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