

Ribociclib MONALEESA-3

PRELIMINARY SCORE

CURATIVE



NON-CURATIVE



ADJUSTMENTS

Quality of life



No QoL benefit



Serious and disabling adverse effects



Other adjustments



Ribociclib MONALEESA-3

FINAL SCORE

CURATIVE

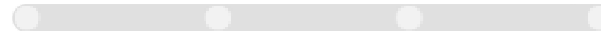


Overall Survival / Disease-Free Survival / Pathological Complete Response

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: Treatment of women with hormone receptor-positive, HER2-negative locally advanced or MBC as initial endocrine-based therapy, or in women who have received prior ET

Experimental Arm: Ribociclib + Fulvestrant

Control Arm: Placebo + fulvestrant

