

Abemaciclib MONARCH 3

PRELIMINARY SCORE

CURATIVE



NON-CURATIVE



ADJUSTMENTS

Quality of life



No QoL benefit



Serious and disabling adverse effects



Other adjustments



Mature OS NS with secondary QoL showing no improvement



Abemaciclib MONARCH 3

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: First-line treatment of hormone receptor-positive, HER2-negative locally advanced or metastatic breast cancer. FDA: Abemaciclib in combination with an aromatase inhibitor as initial endocrine-based therapy for postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer
Experimental Arm: Abemaciclib + Aromatase inhibitor
Control Arm: Placebo + aromatase inhibitor



