

Abemaciclib monarchE

PRELIMINARY SCORE

CURATIVE



NON-CURATIVE



ADJUSTMENTS

Quality of life



Serious and disabling adverse effects



Other adjustments



Abemaciclib monarchE

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: In combination with endocrine therapy is indicated for the adjuvant treatment of adult patients with hormone receptor positive, HER2- negative, node positive early breast cancer at high risk of recurrence and a Ki-67 score >20% In pre or perimenopausal women, aromatase inhibitor endocrine therapy should be combined with a luteinising hormone-releasing hormone agonist
 Experimental Arm: Abemaciclib + Standard endocrine therapy (aromatase inhibitors and/or antiestrogens with or without ovarian suppression)
 Control Arm: Standard endocrine therapy



