

Alpelisib SOLAR-1

PRELIMINARY SCORE

CURATIVE



NON-CURATIVE



ADJUSTMENTS

Quality of life



No QoL benefit



Serious and disabling adverse effects



Increased toxicity



Other adjustments



Mature data shows no OS advantage and no improved QoL



Alpelisib SOLAR-1

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 postmenopausal women, and men, with hormone receptor-positive, HER2-negative, locally advanced or MBC with a PIK3CA mutation after disease progression following ET as monotherapy
 Experimental Arm: Alpelisib + Fulvestrant
 Control Arm: Placebo + fulvestrant



