

Olaparib SOLO-1

PRELIMINARY SCORE

CURATIVE



NON-CURATIVE



ADJUSTMENTS

Quality of life



No QoL benefit

Serious and disabling adverse effects



Other adjustments



Long-term plateau in the PFS curve



Olaparib SOLO-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

Tumour type: Gynaecological Malignancies

Therapeutic Indication: Maintenance treatment of adult patients with advanced (FIGO stages III and IV) BRCA1/2-mutated (germline and/or somatic) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy

Experimental Arm: Olaparib

Control Arm: Placebo



