Olaparib PAOLA-1

PRELIMINARY SCORE

CURATIVE

NON-CURATIVE

PFS

ADJUSTMENTS

Quality of life

No QoL benefit

Serious and disabling adverse effects

Other adjustments

Only improved PFS mature data shows no OS advantage and no improved QoL

Olaparib PAOLA-1

SCORE

CURATIVE

Overall Survival / Disease-Free Survival / Pathological Complete Response

NON-CURATIVE

Overall Survival

2

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) 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 in combination with bevacizumab and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either a BRCA1/2 mutation and/or genomic instability
Experimental Arm: Olaparib + Bevacizumab
Control Arm: Placebo + bevacizumab