

Olaparib

PROpel

PRELIMINARY SCORE

CURATIVE



NON-CURATIVE



ADJUSTMENTS

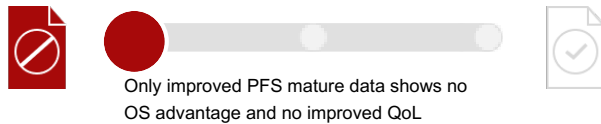
Quality of life



Serious and disabling adverse effects



Other adjustments



FINAL SCORE

CURATIVE



Overall Survival / Disease-Free Survival / Pathological Complete Response

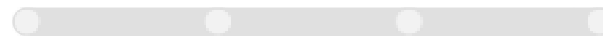
NON-CURATIVE



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: Genitourinary Cancers

Therapeutic Indication: EMA: Olaparib is indicated in combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with mCRPC in whom chemotherapy is not clinically indicated. FDA: olaparib with abiraterone and prednisone (or prednisolone) for adult patients with deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC).

Experimental Arm: Olaparib + Abiraterone and prednisone or prednisolone

Control Arm: Placebo + abiraterone and prednisone or prednisolone

