

Enzalutamide EMBARK

PRELIMINARY SCORE

CURATIVE



NON-CURATIVE



ADJUSTMENTS

Quality of life



No QoL benefit



Serious and disabling adverse effects



Other adjustments



Enzalutamide EMBARK

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: As monotherapy or in combination with androgen deprivation therapy for the treatment of adult men with high risk biochemical recurrent (BCR) non-metastatic hormone sensitive prostate cancer (nmHSPC) who are unsuitable for salvage radiotherapy. Combination group

Experimental Arm: Enzalutamide + Leuprolide

Control Arm: Placebo + Leuprolide



