EORTC GUCG

# Abstract TPS5150: EORTC GUCG 2238 “DE-ESCALATE”, a Pragmatic Trial to Revisit Intermittent Androgen Deprivation Therapy (ADT) in Metastatic Hormone Sensitive Prostate Cancer (mHSPC) in the Era of New AR Pathway Inhibitors (ARPI).

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## BACKGROUND

The standard of care in patients (pts) with mHSPC is ADT + ARPI +/- docetaxel. These ADT + ARPI combinations (also called maximum androgen blockade, MAB) continue until progression, exposing pts to chronic side effects affecting their quality of life (QoL) and increasing costs.

Several sub-analyses of the registration trials demonstrated that pts achieving a PSA ≤ 0.2 ng/ml have prolonged overall survival (OS).

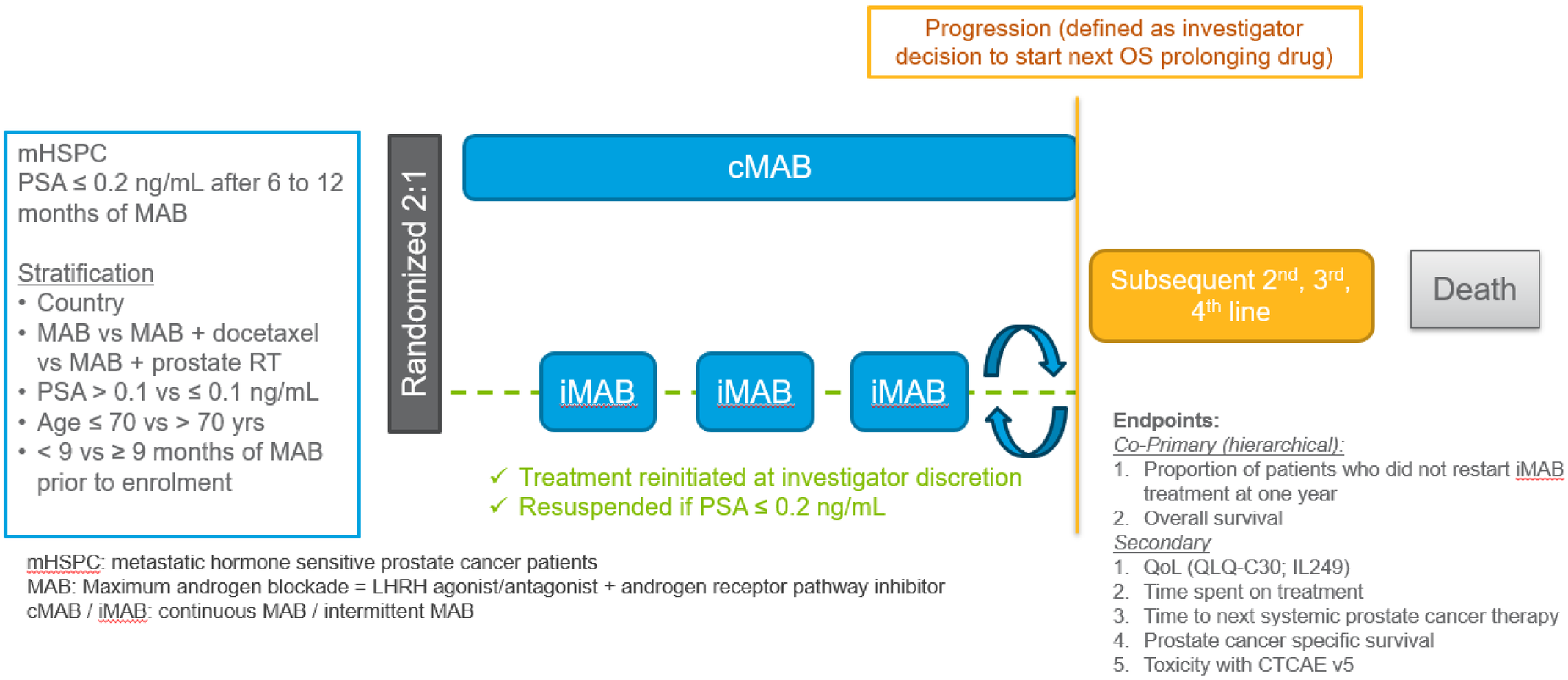
In this study, we hypothesized that pts with mHSPC treated with MAB reaching PSA ≤ 0.2 ng/ml 6-12 months after the start of MAB may benefit from treatment interruption leading to improved QoL and reduced resource use without compromising OS.

## METHODS

EORTC GUCG 2238 “DE-ESCALATE” is a pragmatic, randomized phase III study enrolling patients with mHSPC who reached a PSA ≤ 0.2 ng/ml 6-12 months after the start of MAB. In this study 1600 patients will be randomized to continuous MAB (cMAB) vs intermittent MAB (iMAB).

Co-primary endpoints are hierarchical:
1) The proportion of patients in the iMAB that did not restart the treatment at one year; 2) Overall survival

Secondary endpoints include quality of life with QLQ-C30, IL249; time spent on treatment; time to next systemic prostate cancer therapy; toxicity with CTCAE v5 and health economic parameters (e.g. incremental cost effectiveness ratio).




## CURRENT STATUS

The study is currently active in Belgium, Croatia, Denmark, Ireland, France, Spain and Switzerland.

We are currently awaiting approvals in Czech Republic, Italy, Romania and Slovenia

So far 211 patients were included (Updated May 01, 2026).

## CONCLUSION

EORTC GUCG 2238 “DE-ESCALATE” is a pragmatic phase III randomized control trial that will evaluate the feasibility of a de-escalation strategy in patients with mHSPC that present an excellent PSA response after 6-12 months of MAB.