NEW CLINICAL TRIAL OPEN FOR INCLUSION

PROTOCOL TITLE

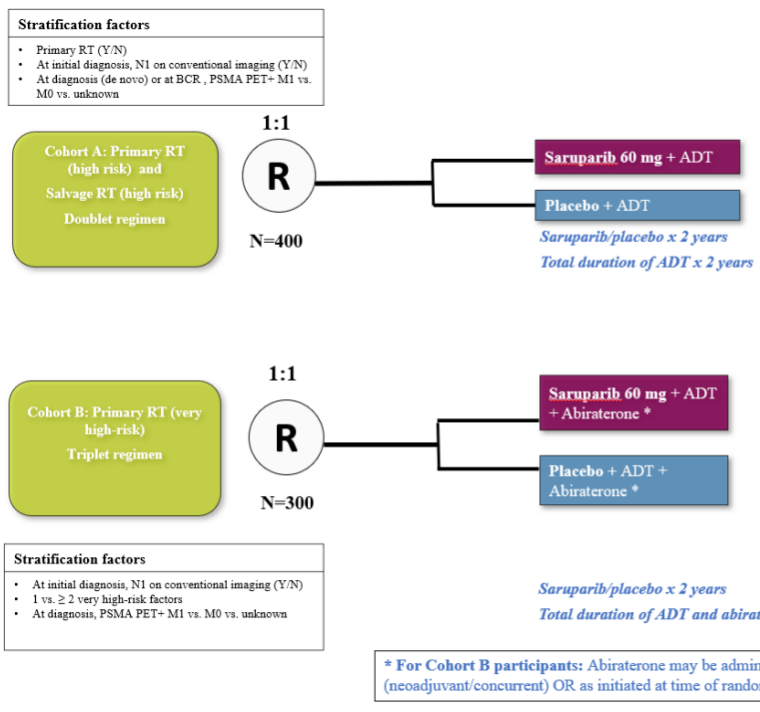
A Randomised, Double-blind, Placebo-controlled, Phase III Study of Adjuvant Saruparib (AZD5305) in Patients with BRCAm Localised High-Risk Prostate Cancer Receiving Radiotherapy with Androgen Deprivation Therapy

ALIAS	CTO NUMBER	SPONSOR
EvoPAR-Prostate02	CTO24101AST	AstraZeneca

KEY INCLUSION AND EXCLUSION CRITERIA

Men with newly diagnosed high-risk prostate adenocarcinoma (de novo) or participants with a high-risk BCR following radical prostatectomy. Patients must have a confirmed BRCA1 or BRCA2 mutation. All participants will have received either primary or salvage RT and a planned regimen of ADT with a GnRH analogue.

DESIGN



Endpoint	Measure
Primary	MFS using standard clinical imaging (conventional imaging or PSMA-PET) by BICR
Secondary	OS (key secondary endpoint) MFS by conventional imaging by BICR MFS by PSMA-PET by BICR Time to biochemical recurrence Prostate cancer-specific survival PFS2 AEs PK PRO (urinary and functional deterioration)

PSA measurement:
- Every 12 weeks from randomization until disease progression

Imaging assessment:
- 48 weeks (midpoint of study treatment)
- At time of biochemical recurrence then every 6 months until progression (MFS)

*** For Cohort B participants:** Abiraterone may be administered as a pre-study regimen with RT (neoadjuvant/concurrent) OR as initiated at time of randomization as an adjuvant only regimen

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