A PHASE 2 TRIAL OF ADT INTERRUPTION IN PATIENTS RESPONDING EXCEPTIONALLY TO AR-PATHWAY INHIBITOR IN METASTATIC HORMONE-SENSITIVE PROSTATE CANCER (MHSPC): A-DREAM

Key Eligibility Criteria (see Section 3.0)

Histologic or clinical diagnosis of metastatic prostate cancer
Currently receiving testosterone suppression (TS) and potent ARPI for mHSPC
Evidence of metastatic disease by conventional imaging prior to starting intense ADT
On TS for mHSPC for 540-750 days without breaks; on ARPI for ≥ 360 days with breaks up to 28 days allowed.
Prior intermittent ADT, prior local therapy, prior RT to metastatic sites permitted.
No prior surgical castration, no ARPI prior to mHSPC diagnosis, no experimental treatment for mHSPC.
Age >= 18 years, ECOG 0-2
Not participating in a clinical trial that does not allow for TS or ARPI interruption
No currently active second malignancy

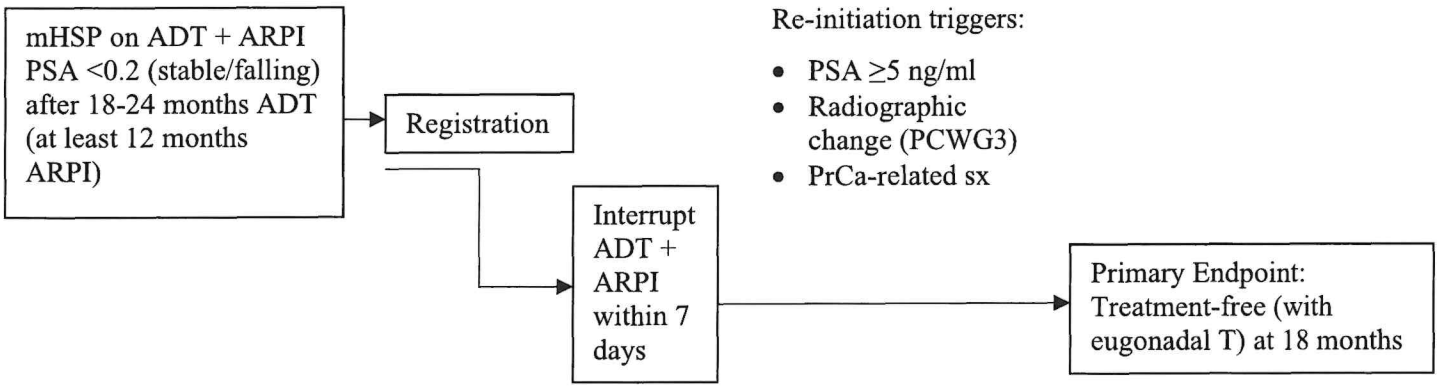
Required Laboratory Values Prior to Initiation of ADT

PSA	≥ 5 ng/ml (does not need to be the most recent value prior to enrollment)
Testosterone	≥ 150 ng/dl or not known to have been hypogonadal (if patient previously received TS, documentation of testosterone ≥ 150 ng/dl is required)

Required Laboratory Values at Enrollment

PSA:	< 0.2 ng/ml (stable or falling for 3 consecutive measurements)
Testosterone:	<50 ng/dl

Schema



Treatment is re-initiated per the pre-specified triggers (PSA increase to ≥ 5 ng/ml, radiographic change [PD on CT/MRI imaging per modified RECIST 1.1 or PDu on bone scintigraphy per PCWG3], or symptoms attributable to prostate cancer). Subsequent management is per physician discretion. Patients undergo protocol assessments until a new treatment is initiated after the initial ARPI is permanently discontinued (i.e. at time to next treatment [TTNT]), and are subsequently followed until withdrawal of consent or death.