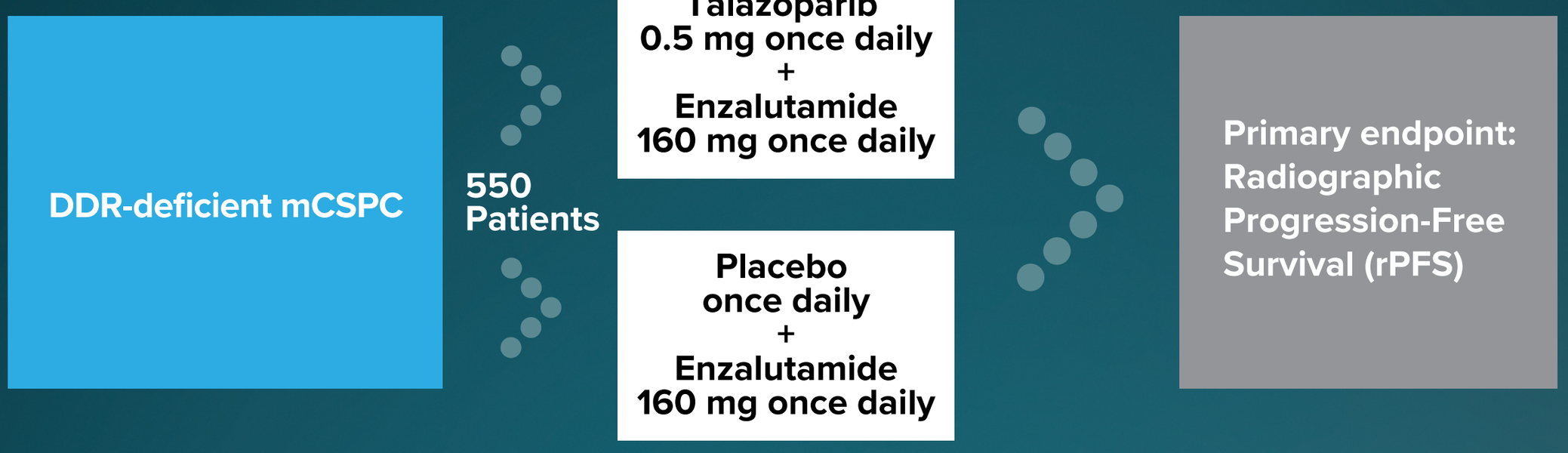
This document contains medical and scientific information on off-label use of talazoparib in combination with enzalutamide

NOW ENROLLING IN METASTATIC CASTRATION-SENSITIVE PROSTATE CANCER

TALAPRO-3

A phase 3, randomized, double-blind, placebo-controlled study of the investigational use of talazoparib with enzalutamide in men with DNA damage response (DDR) gene-mutated metastatic castration-sensitive prostate cancer (mCSPC)



PRIMARY ENDPOINT

Radiographic PFS

SECONDARY ENDPOINTS

- Overall survival
- Objective response rate
- Duration of soft tissue response
- PSA response
- Time to PSA progression
- Safety
- Patient-reported outcomes
- Pharmacokinetics

KEY INCLUSION CRITERIA

- Males at least 18 years of age. For Japan, at least 20 years of age. For Republic of Korea, at least 19 years of age.
- Histologically or cytologically confirmed adenocarcinoma of the prostate
- Confirmation of DDR-deficient status by a gene mutation biomarker panel
- Bilateral orchiectomy or ongoing androgen deprivation therapy (ADT) with a gonadotropin-releasing hormone (GnRH) agonist/antagonist, with serum testosterone ≤50 ng/dL (≤1.73 nmol/L) at screening
- Metastatic disease in bone documented on bone scan or in soft tissue documented on CT/MRI scan
- ECOG performance status 0 or 1

KEY EXCLUSION CRITERIA

- Prior treatment with a PARP inhibitor
- Prior treatment with platinum-based therapy within 5 years prior to randomization for prostate cancer
- History of seizure or any condition that may predispose to seizure
- Known or suspected brain metastasis or active leptomeningeal disease
- Symptomatic or impending spinal cord compression or cauda equina syndrome
- Clinically significant cardiovascular disease
- Significant renal, hepatic, or bone marrow organ dysfunction
- Active COVID-19 infection detected by viral test or based on clinical diagnosis

NOTE: These are not the complete inclusion/exclusion criteria. For more information about this trial, please visit www.clinicaltrials.gov (NCT04821622).

The safety and efficacy of the investigational use of talazoparib and the combination of talazoparib and enzalutamide in metastatic castration-sensitive prostate cancer have not been determined. The investigational use of talazoparib and the combination of talazoparib and enzalutamide in metastatic castration-sensitive prostate cancer have not been approved by any regulatory agency. Please refer to SmPC or marketing authorization for approved use/indication of talazoparib and enzalutamide.

DDR=DNA damage response alterations in genes involved directly or indirectly in homologous recombination repair (HRR); ECOG=Eastern Cooperative Oncology Group; PARP=poly (ADP-ribose) polymerase; PSA=prostate-specific antigen.

This information is current as of May 2022.

Pfizer Oncology