Investigating Apatorsen in Metastatic Castrate-Resistant Prostate Cancer in Combination with Abiraterone

Phase 2 Trial
Pacific
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An investigator-sponsored, randomized Phase 2 trial evaluating apatorsen in men with metastatic castrate-resistant prostate cancer (CRPC) who are experiencing rising prostate-specific antigen (PSA) while receiving Zytiga® (abiraterone acetate)

About apatorsen and the ORCA Program

Apatorsen is a once-weekly intravenous (IV) drug designed to inhibit production of heat shock protein 27 (Hsp27) to disable cancer cells' defenses and overcome treatment resistance. Both the potential single-agent activity of apatorsen and its synergistic activity with cancer treatments may increase the overall benefit of existing therapies and augment the durability of treatment outcomes, which could lead to increased patient survival.

The ORCA™ (**O**ngoing Studies Evaluating Treatment **R**esistance in **CA**ncer) Program encompasses clinical studies of apatorsen aiming to demonstrate whether inhibition of Hsp27 may lead to improved prognoses and treatment outcomes for patients with cancer.

About the Pacific Trial

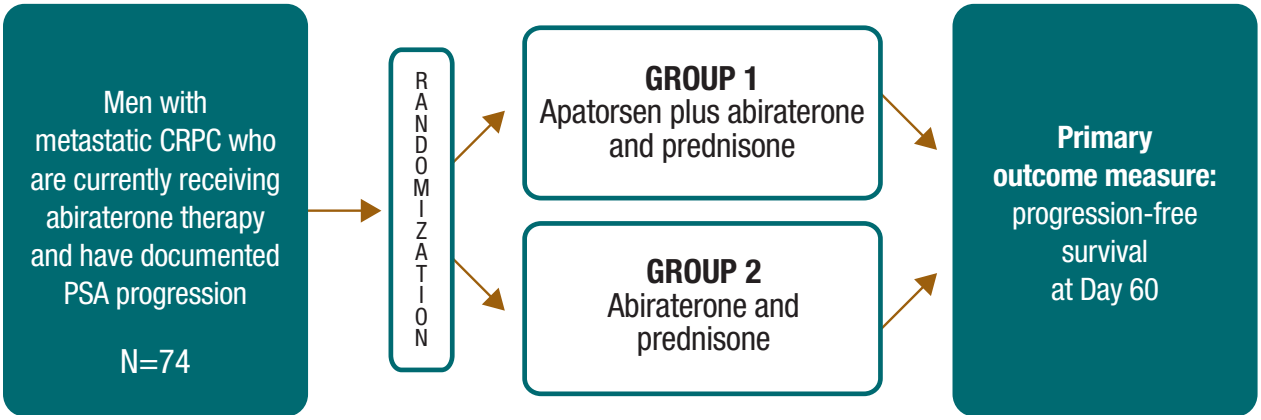
Study population: Men with metastatic CRPC who are currently receiving abiraterone therapy and have documented PSA progression

Primary objective: To ascertain whether adding weekly IV infusions of apatorsen to daily treatment with abiraterone and prednisone results in a greater proportion of patients observed to be alive without progressive disease (PD) at Day 60 (±7 days) compared to continuing daily treatment with abiraterone and prednisone alone

Secondary objectives:

- PSA response
- Progression-free survival
- Circulating tumor cell counts
- PTEN deletion status correlated with clinical outcomes
- Objective response
- Time to disease progression
- Serum Hsp27 and clusterin levels

Study design



- After documented disease progression, group 2 patients may cross over to group 1 treatment
- Both groups will be evaluated at 4-week intervals and at the milestone Day 60 assessment or until documented disease progression

Key inclusion criteria

- Histological or cytological diagnosis of adenocarcinoma of the prostate
- Metastatic disease on CT scan and/or bone scan
- Currently receiving abiraterone and prednisone and meeting the following criteria:
  - Prior PSA response of ≥30%
  - PSA progression, defined as an increase in PSA which is ≥25% above the nadir and an absolute value of ≥2 ng/mL, which is confirmed by a second value ≥2 weeks later
  - No evidence of symptomatic or radiographic progression
- Eastern Cooperative Oncology Group (ECOG) Performance Status (PS) score of 0 or 1
- Patient must fulfill "Prior Therapy" criteria, including:
  - No more than 1 prior chemotherapy regimen
  - Hormonal androgen ablation therapy prior to abiraterone is required
  - Prior non-cytotoxic experimental therapy is permitted. Prior treatment with enzalutamide (MDV3100) is allowed
- Adequate bone marrow, hepatic, and renal function

Key exclusion criteria

- Currently receiving abiraterone in combination with any other anticancer agent (except prednisone)
- Documented brain metastases or carcinomatous meningitis
- Active second malignancy
- Cord compression requiring surgery or radiation therapy
- Active autoimmune disease requiring treatment
- Participated in prior Phase 3 clinical trial evaluating clusterin

ORCA
Ongoing Studies Evaluating Treatment Resistance in CAncer

For more information on the Pacific Trial, please visit www.clinicaltrials.gov (Identifier: NCT01681433) or contact the Hoosier Oncology Group, the study sponsor.

For more information on apatorsen and the ORCA Program, please visit www.ORCAtrials.com
Apatorsen is not approved for commercial use and is only available for investigational use in approved clinical trials.

OncoGenex™