CLINICAL TRIALS IN PROGRESS

PANTHER TRIAL

TITLE : Prospective Study of Apalutamide and Abiraterone Acetate iN ChemoTHerapy-Naïve MEn With mCRPC Stratified by Race (PANTHER; NCT03098836)

BACKGROUND: African American or Black men are underrepresented in nearly all therapeutic trials in advanced prostate cancer. Our recently concluded AbiRace trial (Clinicaltrials.gov NCT01940276) enrolled 50 Black and 50 white men, revealing provocative differences in prostate-specific antigen (PSA) response, progression, and adverse effect rates.

The PANTHER trial follows a similar format with men with metastatic castration-resistant prostate cancer (mCRPC) stratified by race. All patients receive free treatment with abiraterone acetate, an androgen ligand synthesis inhibitor, and with apalutamide, an androgen receptor inhibitor, to enhance androgen-deprivation therapy (ADT). Our goal is to determine if there are any race-driven differences in the efficacy of this combination.

The end points are radiographic progression-free survival and PSA kinetics, time to nadir, and percentage of men who achieve a PSA less than 0.1 ng/mL. We will also estimate the rate of objective response and the incidence of bone flares; measure safety and tolerability, particularly incidence and grade of hypertension; and evaluate overall survival in Black and White men. Exploratory end points revolve around development and validation of genetic biomarkers for disease prognosis and determination of treatment efficacy.

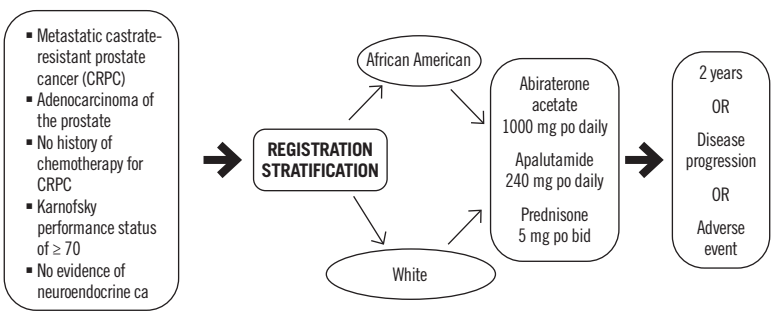
PANTHER is an investigator-initiated trial, funded by Janssen (investigational new drug application #134175; NCT03098836). This study has opened within the Department of Defense Prostate Cancer Clinical Trials Consortium.

INCLUSION CRITERIA: Self-reported Black or White men are eligible if they possess mCRPC disease based on RECIST 1.1 criteria with PSA greater than 2.0 ng/ml. Evidence of mCRPC in the setting of ongoing ADT should be met by at least 1 of these criteria: (1) absolute rise in PSA of 2.0 ng/mL or an increase or more than 25% from the nadir; (2) minimum of 2 consecutive rising PSA levels with an interval of 1 or more weeks between each PSA level; (3) CT- or MRI-based evidence of disease progression (soft tissue, nodal, or visceral disease progression); or (4) at least 1 new bone scan lesion compared with the most immediate prior radiologic studies. Patient should have adequate laboratory parameters. Prior systemic chemotherapy, immunotherapy, or treatment with abiraterone acetate, enzalutamide, apalutamide, galaterone (TOK-001), orteronel (TAK-700), or similar agent is not allowed. Patients with prior chemotherapy for hormone-sensitive prostate cancer are allowed.

PATIENT ACCRUAL INFORMATION

- Accrual goal: 100
- Percent accrued: 88% accrual completed. Forty-nine White and 39 Black men have been enrolled so far, with 11 slots remaining.

STUDY SITES: A total of 8 sites are open to accrual: Duke University Medical Center, Duke Cancer Network, Virginia Oncology Associates, Karmanos Cancer Institute, Spartanburg Veterans Administration Medical Center, University of North Carolina Lineberger Cancer Center, Tulane University, and Chesapeake Urology Research Associates.



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