Testing the Addition of Docetaxel (Chemotherapy) to the Usual Treatment (Hormonal Therapy and Apalutamide) for Metastatic Prostate Cancer, ASPIRE Trial

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Documentation of disease: * Histologically or cytologically confirmed adenocarcinoma of the prostate without small cell histology * Must have had evidence of metastatic disease (American Joint Committee on Cancer \[AJCC\] metastasis \[M\]1 disease) based on conventional CT/MRI and/or bone scan. This will be defined as: * Bone metastases detected by CT, radionuclide technetium-99 (99Tc)- methylene bisphosphonate bone scan, or MRI as defined by PCWG3 criteria; OR * Non-pelvic lymph node metastases (measurable lymph nodes above the aortic bifurcation; lymph nodes are measurable if the short axis diameter is ≥ 15 mm) detected on CT or MRI as defined by Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1. Subjects with regional lymph node metastases only (nodes \[N\]1, below the aortic bifurcation) will not be eligible for the study; OR * Visceral or soft tissue metastases detected on CT or MRI as defined by RECIST version 1.1. Soft tissue/visceral lesions are measurable if the long axis diameter is ≥ 10 mm * Evidence of metastatic disease by PSMA-PET only and not visible by CT, radionuclide bone scan, or MRI will not satisfy eligibility criteria * No metachronous low-volume disease (defined as recurrent metastatic disease after definitive treatment of prostate primary) and with ≤ 4 bone metastasis and no visceral metastasis on conventional imaging by CT, radionuclide 99Tc-biphosphonate bone scan, or MRI) * Next generation sequencing (NGS) results from any tissue based Clinical Laboratory Improvement Act (CLIA) test must be available at the time of registration. NGS from soft tissue or visceral lesion if available is preferred. NGS from bone or primary prostate will be accepted. Patients with failed NGS testing are not eligible * Prior treatment * ADT (luteinizing hormone-releasing hormone \[LHRH\] agonist/antagonist or orchiectomy) with or without first generation anti-androgen, or second-generation androgen receptor signaling inhibitor (ARSI) within 120 days of registration is permitted. No washout period will be needed for the first generation- androgen or ARSI prior to registration. Anti-androgen treatment is only permitted if used within 120 days of registration * No prior chemotherapy for prostate cancer * Age ≥ 18 years * Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2 * Absolute neutrophil count (ANC) ≥ 1,500/mm\^3 * Hemoglobin ≥ 9.0 g/dL * Platelet count ≥ 100,000/mm\^3 * Total bilirubin ≤ 1 x upper limit of normal (ULN) (Note: In subjects with Gilbert's syndrome, if total bilirubin is \> 1.5 × ULN, measure direct and indirect bilirubin and if direct bilirubin is ≤ 1 × ULN, subject may be eligible) * Aspartate aminotransferase (AST) (serum glutamic oxaloacetic transaminase \[SGOT\])/alanine aminotransferase (ALT) (serum glutamate transaminase \[SGT\]) ≤ 1.5 x upper limit of normal (ULN) * Calculated (Calc.) creatinine clearance \> 30 mL/min * Serum potassium ≥ 3.5 mmol/L * Comorbid conditions * Patients with a prior or concurrent malignancy whose natural history or treatment does not have the potential to interfere with the safety or efficacy assessment of the investigational regimen are eligible for this trial * Leptomeningeal metastases: Patients with treated leptomeningeal metastases are eligible if follow-up brain imaging 30 days after central nervous system (CNS)-directed therapy shows no evidence of progression * HIV: Patients with known HIV infection on effective anti-retroviral therapy with undetectable viral load within 6 months prior to registration are eligible for this trial * Hepatitis B: For patients with evidence of chronic hepatitis B virus (HBV) infection, the HBV viral load must be undetectable on suppressive therapy, if indicated * Hepatitis C: Patients with a history of hepatitis C virus (HCV) infection must have been treated and cured. For patients with HCV infection who are currently on treatment, they are eligible if they have an undetectable HCV viral load * No seizure or known condition that may pre-dispose to seizure (e.g. prior stroke within 1 year to randomization, brain arteriovenous malformation or condition requiring CNS surgery or radiation therapy) * Patients with known history or current symptoms of cardiac disease, or history of treatment with cardiotoxic agents, should have a clinical risk assessment of cardiac function using the New York Heart Association functional classification. To be eligible for this trial, patients should be class II or better. Any condition that in the opinion of the investigator, would preclude participation in this study. Patients with stable asymptomatic deep venous thromboembolism on stable anti-coagulation will be eligible * Hypertension: Subjects with uncontrolled hypertension as indicated by a resting systolic blood pressure (BP) \>= 160 mmHg or diastolic BP \>= 100 mmHg despite medical management are not permitted to register * Allergies: Subjects with known hypersensitivity to any of the study drugs, or excipients in the formulation of the study drugs are not permitted to register * Concomitant medications * Chronic concomitant treatment with strong inhibitors of cytochrome P450 3A4 (CYP3A4) is not allowed on this study. Patients on strong CYP3A4 inhibitors must discontinue the drug prior to registration on the study. See Section 8.1.9 for more information * Chronic concomitant treatment with strong CYP3A4 inducers is not allowed. Patients must discontinue the drug 14 days prior to the start of study treatment * Medications known to lower the seizure threshold must be discontinued or substituted prior to study entry. See Section 8.1.9 for more information * Patient agrees to use a condom (even men with vasectomies) and another effective method of birth control if having sex with a woman of childbearing potential or agrees to use a condom if having sex with a woman who is pregnant while on study drug and for 3 months following the last dose of study drug. Must also agree not to donate sperm during the study and for 3 months after receiving the last dose of study drug

Conditions & Interventions

Interventions:

DRUG: Androgen Therapy, DRUG: Apalutamide, DRUG: Docetaxel, PROCEDURE: Computed Tomography, PROCEDURE: Magnetic Resonance Imaging, PROCEDURE: Bone Scan, PROCEDURE: PSMA PET Scan, PROCEDURE: Biospecimen Collection, OTHER: Questionnaire Administration

Conditions:

Castration-Sensitive Prostate Carcinoma, Metastatic Prostate Adenocarcinoma, Stage IVB Prostate Cancer AJCC v8

More Information

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Principal Investigator:

IRB

Number:

System ID: NCT06931340