Targeted Treatment for Metastatic Prostate Cancer, The PREDICT Trial

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* PRE-REGISTRATION: Histological or cytological evidence of prostate cancer. Patients with variant histologies including neuroendocrine, small cell and sarcomatoid prostate cancer are allowed to enroll and these will not be used as selection criteria for individual arms. Central pathology review is not required. * PRE-REGISTRATION: Measurable disease and/or non-measurable metastatic disease per RECIST version 1.1. * PRE-REGISTRATION: Tissue procured within 12 months of pre-registration (metastatic disease preferred over primary tissue, though both are acceptable) available for submission per Section 6.2. For patients who have progressed on A032102 and are pre-registering again, repeat tissue procurement will not be mandated. * PRE-REGISTRATION: Molecular report available performed as part of standard of care testing via any Clinical Laboratory Improvement Act (CLIA)-certified next generation sequencing (NGS) assay. Patients may be assigned based on pre-determined qualifying molecular/DNA alterations as stated in Section 4.8 after receipt of local molecular testing by the A032102 molecular tumor board (MTB). Final determination of arm assignment will be determined by the MTB. For qualifying DNA alteration determined by the MTB, testing may be from tumor tissue collected at any time or circulating tumor DNA (ctDNA) within 12 months of pre-registration. If no qualifying DNA alteration is identified based on the CLIA-certified next generation sequencing assay and MTB review, Caris testing, should be performed for both DNA/RNA profiling. Arm assignment based RNA requires testing of tumor tissue collected within 12 months of pre-registration and MTB review. * PRE-REGISTRATION: Age ≥ 18 years. * REGISTRATION: Progressive mCRPC as defined: 1) castrate levels of serum testosterone \< 50 ng/dL AND one or more of the following criteria (choose all the apply): * PSA progression, defined by at least 2 consecutive rising PSA values at a minimum of 1-week intervals with the most recent PSA value being 2.0 ng/mL or higher, if confirmed PSA rise is the only indication of progression. Patients who received an anti-androgen must have PSA progression after withdrawal of anti-androgen therapy. * Radiographic progression per RECIST 1.1 criteria for soft tissue lesions * Bone metastasis progression per Prostate Cancer Working Group 3 (PCWG3) criteria. * REGISTRATION: Patients selected to receive lutetium Lu 177 vipivotide tetraxetan treatment are required to have prostate-specific membrane antigen (PSMA) positive mCRPC as determined by investigator assessment. For reference, in the VISION trial this was defined as at least 1 PSMA+ metastatic lesion (defined as uptake greater than that of liver parenchyma in lesions of any size in any organ system) and no PSMA- lesions (defined as uptake equal to or lower than that of liver parenchyma in any lymph node with a short axis of at least 2.5 cm, in any solid organ lesion with a short axis of at least 1.0 cm, or in any bone lesion with a soft-tissue component of at least 1.0 cm in the short axis). * REGISTRATION: Prior treatment with androgen receptor signaling inhibitor (ARSI) in either the metastatic hormone sensitive setting or mCRPC is required. Prior taxane therapy in either metastatic hormone sensitive setting or mCRPC is mandated unless patient is taxane ineligible or the patient refuses taxane therapy. Prior lutetium LU177 vipivotide tetraxetan treatment is permitted but not mandated. Patients with known germline or somatic deleterious BRCA 1/2 mutations must have received a prior PARPi. * REGISTRATION: Resolved toxicities from previous anticancer therapy, defined as toxicities (other than alopecia) resolved to Common Terminology Criteria for Adverse Events (CTCAE) version 5.0, grade ≤ 1 or baseline. Note: Subjects may be enrolled with chronic, stable grade 2 toxicities (defined as no worsening to \> grade 2 for at least 3 months prior to registration and managed with standard of care treatment) that the investigator deems related to previous anticancer therapy, comprised of: * Chemotherapy-induced neuropathy * Fatigue * Residual toxicities from prior treatment: Grade 1 or grade 2 endocrinopathies which may include: Hypothyroidism/hyperthyroidism. type I diabetes, hyperglycemia, adrenal insufficiency, adrenalitis, skin hypopigmentation (vitiligo) * REGISTRATION: No cytotoxic, biologic, radiopharmaceutical or other non-kinase inhibitor investigational agent within 4 weeks of registration. Treatment with any type of small molecular kinase inhibitor (including investigational kinase inhibitor) within 2 weeks of registration. Treatment with abiraterone acetate, apalutamide, or darolutamide within 2 weeks of registration. Treatment with enzalutamide within 4 weeks of registration. No treatment with radiation therapy within 2 weeks of registration. * REGISTRATION: No major surgery within 4 weeks of registration. * REGISTRATION: No prior treatment with EZH inhibitors. * REGISTRATION: Prior treatment with cabazitaxel + carboplatin. * REGISTRATION: None of the following conditions: * Current use of moderate or strong cytochrome P450 (CYP)3A inducers. * Known or suspected hypersensitivity to valemetostat tosylate (DS-3201b) or any of the excipients. * For patients with evidence of chronic hepatitis B virus (HBV) infection, the HBV viral load must be undetectable on suppressive therapy, if indicated. 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. * HIV-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months are eligible for this trial. * Imminent or established spinal cord compression based on clinical and/or imaging findings. * Known brain metastases or cranial epidural disease unless adequately treated with radiotherapy and/or surgery (including radiosurgery) and stable for at least 4 weeks prior to registration after radiotherapy or at least 4 weeks prior to registration after major surgery (e.g., removal or biopsy of brain metastasis). Patients must have complete wound healing from major surgery or minor surgery before registration. * Significant cardiovascular defined as: * Myocardial infarction within 6 months prior to enrollment. * Uncontrolled angina pectoris within 6 months prior to enrollment. * New York Heart Association Class 3 or 4 congestive heart failure. * Corrected QT interval calculated by the Fridericia\'s formula (QTcF) ≥ 470 ms per electrocardiogram (ECG) within 42 days before randomization in any individual with any history of any cardiac disease or medication which can impact QTcF. Patients with known history or current symptoms of cardiac disease, history of treatment with cardiotoxic agents, or agents/conditions known to impact QTcF should have a clinical risk assessment of cardiac function using the New York Heart Association Functional Classification and ECG. * Uncontrolled hypertension (resting systolic blood pressure \>160 mmHg or diastolic blood pressure \> 100 mmHg). * Clinically significant acute infection requiring systemic antibacterial, antifungal or antiviral therapy. * Moderate to severe hepatic impairment (Child-Pugh Class C) * REGISTRATION: No freezing or donating sperm ≤ 14 days prior to registration. * REGISTRATION: Eastern Cooperative Oncology Group (ECOG) performance status 0-2. * REGISTRATION: No granulocyte colony-stimulating factor (GCSF) within 2 weeks of registration. * REGISTRATION: No red blood cell (RBC) transfusions within 2 weeks of registration. * REGISTRATION: No platelet transfusions within 2 weeks of registration. * REGISTRATION: No bleeding diathesis. * REGISTRATION: White blood cell count (WBC) ≥ 2,500/mcL. * REGISTRATION: Absolute neutrophil count (ANC) ≥ 1,500/mcL. * REGISTRATION: Hemoglobin ≥ 9 g/dL. * REGISTRATION: Platelet count ≥ 100,000/mcL. * REGISTRATION: Creatinine clearance ≥ 30 mL/min as defined by Cockcroft-Gault equation. * REGISTRATION: Total bilirubin ≤ 1.5 x ULN (≤ 3 x upper limit of normal \[ULN\] for subjects with documented Gilbert\'s disease). * REGISTRATION: Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) ≤ 3 x ULN. * REGISTRATION: Albumin ≥ 2.8 g/dL. * REGISTRATION: The A032102 molecular tumor board will review the local pathology report and molecular sequencing report, and the Alliance registration/randomization office will relay the assignment to the submitting site. Once the site receives this assignment, they can register the patient to A032102. Any questions about the molecular board treatment assignments can be directed to A032102@alliancenctn.org. * RE-REGISTRATION: Progressive mCRPC (after receiving the tumor board assigned therapy) as defined: 1) castrate levels of serum testosterone \< 50 ng/dL AND 2) progressive disease defined by radiographic progression on conventional imaging (CT/MRI chest, abdomen and pelvis and bone scan within 42 days of re-registration). * RE-REGISTRATION: Resolved toxicities from previous anticancer therapy, defined as toxicities (other than alopecia) resolved to CTCAE version 5.0, grade ≤ 1 or baseline. Note: Subjects may be enrolled with chronic, stable grade 2 toxicities (defined as no worsening to \> grade 2 for at least 3 months prior to registration and managed with standard of care treatment) that the investigator deems related to previous anticancer therapy, comprised of: * Chemotherapy-induced neuropathy * Fatigue * Residual toxicities from prior treatment: Grade 1 or grade 2 endocrinopathies which may include: Hypothyroidism/hyperthyroidism. type I diabetes, hyperglycemia, adrenal insufficiency, adrenalitis, skin hypopigmentation (vitiligo). * RE-REGISTRATION: None of the following conditions: * Imminent or established spinal cord compression based on clinical and/or imaging findings. * Known brain metastases or cranial epidural disease unless adequately treated with radiotherapy and/or surgery (including radiosurgery) and stable for at least 4 weeks prior to registration after radiotherapy or at least 4 weeks prior to re-registration after major surgery (e.g., removal or biopsy of brain metastasis). Patients must have complete wound healing from major surgery or minor

weeks prior to re-registration after major surgery (e.g., removal of biopsy of brain metastasis). Patients must have complete wound healing from major surgery or minor surgery before re-registration. * Corrected QT interval calculated by the Fridericia\'s formula (QTcF) \< 470 ms per ECG within 42 days before randomization in any individual with any history of any cardiac disease or medication which can impact QTcF. * Significant cardiovascular defined as: * Myocardial infarction within 6 months prior to enrollment. * Uncontrolled angina pectoris within 6 months prior to enrollment. * New York Heart Association Class 3 or 4 congestive heart failure. * Uncontrolled hypertension (resting systolic blood pressure \> 160 mmHg or diastolic blood pressure \> 100 mmHg). * RE-REGISTRATION: ECOG Performance Status 0-2. * RE-REGISTRATION: No GCSF within 2 weeks of registration. * RE-REGISTRATION: No RBC transfusions within 2 weeks of registration. * RE-REGISTRATION: No platelet transfusions within 2 weeks of registration. * RE-REGISTRATION: WBC ≥ 2,500/mcL. * RE-REGISTRATION: ANC ≥ 1,500/mcL. * RE-REGISTRATION: Hemoglobin ≥ 9 g/dL (transfusions permitted). * RE-REGISTRATION: Platelet count ≥ 100,000/mcL. * RE-REGISTRATION: Creatinine clearance ≥ 30 mL/min as defined by Cockcroft-Gault equation. * RE-REGISTRATION: Total bilirubin ≤ 1.5 x ULN (≤ 3 x ULN for subjects with documented Gilbert\'s disease). * RE-REGISTRATION: AST and ALT ≤ 3 x ULN. * RE-REGISTRATION: Albumin ≥ 2.8 g/dL. * RE-REGISTRATION: QT Interval (QTcF) \< 470 ms (in individuals with any cardiac history of any medication or condition known to impact QTcF). * RE-REGISTRATION: The A032102 molecular tumor board will review the CARIS molecular sequencing report, the Alliance registration/randomization office will relay the assignment to the site. Any questions about the molecular board treatment assignments can be directed to A032102@alliancenctn.org.

Exclusion Criteria:

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Conditions & Interventions

Interventions:
OTHER: Genetic testing, DRUG: Valemetostat Tosylate, PROCEDURE: Magnetic Resonance Imaging, PROCEDURE: Computed Tomography, PROCEDURE: Bone scan, PROCEDURE: FDG-Positron Emission Tomography, PROCEDURE: PSMA PET Scan, PROCEDURE: Biospecimen Collection, DRUG: Carboplatin, DRUG: Cabazitaxel, DRUG: Abiraterone Acetate, DRUG: Enzalutamide, DRUG: Lutetium Lu 177 Vipivotide Tetraxetan
Conditions:
Castration-Resistant Prostate Carcinoma, Stage IVB Prostate Cancer AJCC v8

More Information

Contact(s): Rana McKay, MD - rmckay@health.ucsd.edu
Principal Investigator:
Phase: PHASE2
IRB
Number:
System ID: NCT06632977
