GZ17-6.02 in Advanced CRPC After Progression on Anti-Androgen Therapy

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Patients diagnosed with prostate cancer and treated with androgen deprivation therapy (ADT) and at least one androgen receptor pathway inhibitor (ARPI) (eg, abiraterone, enzalutamide, apalutamide or darolutamide). Previous prostate-specific membrane antigen (PSMA)-targeted therapy or cytotoxic chemotherapy is allowed but not required. * Androgen levels ≤50 ng/dL (≤1.73 nmol/L). * Disease progression following ADT and ARPI treatment described * PSA progression over 2 assessments, defined as rising PSA values from 2 consecutive assessments with an interval of at least 7 days between assessments. PSA levels prior to study enrollment are considered and appropriate for inclusion. * Measurable disease by RECIST v1.1 on chest/abdomen/pelvis CT or evaluable disease observed on bone scan. * Eastern Cooperative Oncology Group (ECOG) performance status 0, 1, or 2 * Appropriate hepatic function defined by a total bilirubin (TBL) ≤1.5 × the upper limit of normal (ULN), alanine aminotransferase (ALT) AND aspartate aminotransferase (AST) ≤3 × ULN at screening. * Appropriate kidney function defined by calculated or actual creatinine clearance ≥30 mL/min * Absolute neutrophil count (ANC) ≥ 1,500 cells/mm3. * Platelets ≥100,000 cells/mm3. * Serum hemoglobin level ≥9 g/dL. * Agree to not donate blood or sperm during the study and for 90 days after the last dose of study treatment. * Patients with sexual partners of childbearing potential must agree to use highly effective methods of contraception throughout the study * Ability to understand and the willingness to sign a written informed consent document

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Exclusion Criteria:

* Any investigational agent: within 4 weeks OR within a time interval less than at least 5 half-lives of the investigational agent, whichever is shorter, before initiating study treatment. * Low PSA (≤10 ng/mL) at initial presentation (before ADT or at symptomatic progression in the castrate setting) plus high volume (≥20) bone metastases. * Simultaneous enrollment in any other cancer treatment interventional clinical trial. * Active, uncontrolled diarrhea leading to dehydration or electrolyte disturbances not controlled with oral repletion. * Grade ≥3 uncontrolled infection. * Major surgery (in the opinion of the treating investigator) ≤3 weeks before initiating study treatment. * Not having fully recovered to a grade of 1 or lower from any surgery-related adverse effects within the 3 weeks preceding the start of the study treatment. * Small cell, anaplastic, or neuroendocrine component. * Known active brain metastasis. * Known active leptomeningeal disease. * Planned ongoing treatment with other drugs thought to potentially have adverse interactions with either of the medications included in the study treatment must be discontinued ≥2 weeks prior to initiating study treatment unless otherwise noted: * Monoamine oxidase inhibitors (MAOI) use; must discontinue use 10 days prior to initiating study therapy. * Strong or moderate CYP1A2, CYP3A4 and CYP2C19 inhibitors. * Rucaparib, Olaparib and Talazoparib, due to their common findings of liver enzyme elevation. * Inability to swallow medication. * Known hypersensitivity to GZ17-6.02 components (curcumin, harmine, and isovanillin) or excipients. * Known or suspected malabsorption condition or obstruction. * Active untreated hepatitis B or C" and "Known liver cirrhosis of any cause, active nonalcoholic steatohepatitis, or nonalcoholic fatty liver disease. Note: no additional testing necessary to confirm * Medical, psychological, or social condition that, in the opinion of the investigator, may increase the patient's risk or limit the patient's adherence with study requirements

Conditions & Interventions

Interventions:
DRUG: Investigational Agent Administration
Conditions:
Castration-resistant Prostate Cancer

More Information

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Phase: PHASE1
IRB
Number:
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