A Study of Tulmimetostat DZR123 (CPI-0209) in Patients With Advanced Solid Tumors and Lymphomas

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A Phase 1/2 Study of DZR123 (CPI-0209) in Patients With Advanced Solid Tumors and Lymphomas
ClinicalTrials.gov Identifier:
NCT04104776
Novartis Reference Number:CDZR123A02101
See if you Pre-qualify
All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

The purpose of this open-label, first-in-human (FIH) trial is to evaluate the safety, tolerability, and preliminary clinical activity of Tulmimetostat as a monotherapy in patients with advanced solid tumors and lymphomas. The study is divided into Phase 1 and Phase 2. In Phase 1 and the Phase 2 expansion (M1 to M7), patients are non-randomized. In Phase 2 optimization, patients in Cohort M2 and M3 (Stage 2a and 2b) and Cohort M8 (Part 2) are randomized.

Phase 1 of the study is composed of a Tulmimetostat Dose Escalation period in patients with advanced tumors and aims to determine maximum tolerated dose (MTD) and/or recommended Phase 2 dose (RP2D) of Tulmimetostat as monotherapy in patients with advanced tumors.

Phase 2 of the study is planned to evaluate safety and tolerability and antitumor activity of Tulmimetostat in six disease-specific cohorts (M1 to M6). Patients in Cohorts M1, M2, M3, M5, and M6 will be enrolled at 10 to 29 patients per cohort, using a Simon 2-stage design. Cohort M4 will enroll up to 20 patients with lymphoma in a single-stage.

The primary aim of Phase 2 part of the study is to evaluate the antitumor activity of Tulmimetostat, and characterize the safety and tolerability of Tulmimetostat as monotherapy in patients with selected tumors.

In Phase 2, two additional doses are planned to be evaluated in cohorts M2 and M3 in 2 stages: Stage 2a and Stage 2b. In Stage 2a approximately 20 patients will be enrolled per cohort and will be randomized 1:1 to receive 2 prespecified dose levels of Tulmimetostat once daily. When protocol criteria for initiating Stage 2b will be fulfilled after completion of Stage 2a, then Stage 2b will be opened for enrolment of additional 10 patients in one or both dose arms in each of the two cohorts. Thus, up to 40 patients per cohort (M2 and M3) could be enrolled.

The study will explore the Tulmimetostat in anti-tumor activity and effect of food on pharmacokinetics of Tulmimetostat in in patients with ARID1A WT endometrial carcinoma (Cohort M7) and safety and anti-tumor activity of Tulmimetostat in in combination with enzalutamide in patients with mCRPC (Cohort M8).

In Cohort M8 Part 1, the safety and tolerability of Tulmimetostat in and enzalutamide combination will be evaluated in patients with mCRPC. The M8 Part 1 dose escalation incorporates combination of Tulmimetostat in at escalating provisional doses with enzalutamide.

In Cohort M8 Part 2, the safety, tolerability and preliminary antitumor activity of Tulmimetostat at a RP2D in combination with enzalutamide will be further evaluated in patients with mCRPC.

Condition
Advanced Solid Tumor, Diffuse Large B Cell Lymphoma, Lymphoma, T-Cell, Mesothelioma, Malignant, Prostatic Neoplasms, Castration-Resistant, Endometrial Cancer, Ovarian Clear Cell Carcinoma, Metastatic Castration-resistant Prostate Cancer
Phase
Phase1, Phase2
Overall Status
Recruiting
Number of Participants
275
Start Date
Sep 18, 2019
Completion Date
Feb 27, 2030
Gender
All
Age(s)
18 Years - (Adult, Older Adult)

Interventions

Drug

Enzalutamide

Enzalutamide dosed once per day orally in 28 day cycles
Drug

Tulmimetostat

Tulmimetostat dosed once per day orally in 28 day cycles

Eligibility Criteria

Key Inclusion Criteria:

* Eligible Phase 1 patients are adults who have a confirmed locally advanced or metastatic tumors (solid tumors or lymphoma) that have relapsed following standard therapy or progressed through standard therapy or who have a disease for which no standard effective therapy exists.
* Eligible Phase 2 patients in cohorts M1 to M3 are adults who are known to have the ARID1A mutation by next-generation sequencing (NGS) testing; have measurable disease per Response Evaluation Criteria in Solid Tumors 1.1 and who have confirmed relapsed urothelial or other advanced/metastatic solid tumors (M1),

ovarian clear cell carcinoma (M2), or endometrial carcinoma (M3).
* Eligible Phase 2 patients in Cohort M4 are adults who have either relapsed or refractory PTCL (at least 10 patients) or DLBCL (up to 10 patients), including patients with documented GCB DLBCL with EZH2 hotspot mutation. Patients with PTCL must have at least 1 prior line of therapy and patients with DLBCL must have at least 2 prior lines of standard therapy; and are not considered candidates to receive CAR-T or ASCT therapy.
* Eligible Phase 2 patients in Cohort M5 are adults who are known to the have the BAP1 loss, have malignant pleural or peritoneal mesothelioma, and have progressed on at least 1 prior line of active therapy.
* Eligible Phase 2 patients in Cohort M6 are adults who have mCRPC with measurable soft tissue disease with CT scan as defined by PCWG3 criteria, have baseline testosterone levels ≤ 50 ng/dL (≤ 2.0 nM) and have surgical or ongoing medical castration and who have progressed on at least 1 androgen-receptor signaling inhibitor and at least 1 taxane-based chemotherapy (cabazitaxel, France only).
* Eligible Phase 2 patients in Cohort M7 are adults with recurrent, advanced ARID1A WT endometrial carcinoma confirmed by NGS testing and have measurable disease per Response Evaluation Criteria in Solid Tumors 1.1 Patients will be enrolled with maximum up to 2 prior lines of systemic therapy for treating endometrial carcinoma that must include at least one treatment line with systemic platinum-based chemotherapy in advanced/ recurrent disease setting, and anti-programmed cell death protein 1 (PD-1)/ anti-programmed death-ligand 1 (PD-L1) therapy, either in combination or separately, unless these are contraindicated or are not locally accessible.
* Eligible Part 1 and Part 2 patients in Cohort M8 are adults who have mCRPC with measurable soft tissue disease as per PCWG3 criteria, have baseline testosterone levels ≤ 50 ng/dL (≤ 2.0 nM), have surgical or ongoing medical castration or hormone sensitive prostate cancer (HSPC) disease stage. In addition, Eligible part 1 patients in Cohort M8 may have received abiraterone treatment in mCRPC while eligible part 2 patients in Cohort M8 must have received abiraterone treatment in mCRPC. In addition, only for M8 Part 1: Patients may have received no more than one previous regimen of taxane-based chemotherapy in mCRPC or HSPC setting. For M8 Part 2: Patients may have received no more than one previous regimen of taxane-based chemotherapy in HSPC setting. Patients for both M8 Part 1 and M8 Part 2 must have evidence of prostate cancer progression (per PCWG3) and must have ongoing ADT (androgen deprivation therapy) with a GnRH analogue, antagonist or bilateral orchiectomy (i.e., surgical or medical castration).
* All patients will have Eastern Cooperative Oncology Group (ECOG) performance status of ≤ 1 and adequate organ function.

Key Exclusion Criteria:

1. Medical Conditions

* Previous solid organ or allogeneic hematopoietic cell transplantation (HCT).
* Known symptomatic untreated brain metastases. Patients with central nervous system (CNS) metastases must have stable neurologic status following local therapy for at least 4 weeks on a stable or decreasing dose of steroids (≤ 10 mg daily prednisone or equivalent). Patients in the M4 lymphoma cohort are excluded if they have known CNS involvement by lymphoma.
* Clinically significant cardiovascular disease, including:

* Myocardial infarction or stroke within 3 months (6 months for M8 cohort) prior to Day 1 of treatment.
* Unstable angina within 3 months (6 months for M8 cohort) prior to Day 1 of treatment.
* Congestive heart failure or cardiomyopathy with New York Heart Association (NYHA) Class 3 or 4.
* History of clinically significant ventricular arrhythmias (e.g., ventricular tachycardia, ventricular fibrillation, torsades de pointes).
* Uncontrolled hypertension despite 2 concomitant antihypertensive therapies.
* For Cohorts M1-M6: QT interval corrected by the Fridericia correction formula (QTcF) \> 480 msec on the Screening ECG.

* For Cohorts M7 and M8: QTcF interval ≥ 450 msec at screening.
* Major surgery within 4 weeks before starting study drug or not recovered from any effects of prior major surgery (uncomplicated central line placement or fine needle aspirate are not considered major surgery).
* Gastrointestinal disorders that may significantly interfere with the absorption of the study medication, such as ulcerative colitis, malabsorption syndrome, refractory nausea and vomiting, biliary shunt, significant bowel resection.
* Uncontrolled active infection requiring intravenous antibiotic, antiviral, or antifungal medications within 14 days before the first dose of study drug. Controlled infections on concurrent antimicrobial agents and antimicrobial prophylaxis per institutional guidelines are acceptable.
* Suspected pneumonitis or interstitial lung disease (confirmed by radiography or CT) or a history of these conditions.
* History of a concurrent or second malignancy except for certain adequately treated cancers such as local basal cell or squamous cell carcinoma of the skin, cervical carcinoma in situ, superficial bladder cancer, asymptomatic prostate cancer without known metastatic disease, adequately treated Stage 1 or 2 cancer currently in complete remission, or any other cancer in complete remission for ≥ 3 years. Patients with a history of T-cell lymphoblastic lymphoma or T-cell lymphoblastic leukemia are not eligible.
* Current known active or chronic infection with HIV, hepatitis B, or hepatitis C. Screening for these viruses is not required unless there is a past history or current suspicion of viral hepatitis.
* Clinically active or symptomatic viral hepatitis or chronic liver disease.
* Unstable or severe uncontrolled medical condition or any important medical or psychiatric illness or abnormal laboratory finding that would increase the risk to the patient associated with participation in the study.
* For Cohort M7 Only: Patients not willing to or cannot remain fasted due to a medical condition for 2 hours before and 1 hour after dose administration.
2. Prior/Concomitant Therapy:

* Prior Anticancer Treatment:

* Systemic Anticancer Treatment: Patients must not have received chemotherapy, targeted therapy, small molecules, antibodies, investigational anticancer therapy, or other anticancer therapeutics (except gonadotropin-releasing hormone analogues) within 4 weeks (or 5 half-lives, whichever is shorter) before the first dose of the study drug. For nitrosoureas or mitomycin C, a 6-week washout is required. For prior PD-1 or PD-L1 therapy, a washout period of at least 4 weeks is acceptable. All toxicities from prior therapies must have resolved to Grade 1 or less, except for endocrinopathies requiring medication, neuropathy, and alopecia, which must have resolved to Grade 2 or less.
* EZH2 Inhibitor: Previous treatment with an EZH2 inhibitor is not allowed.
* Radiation Therapy: Patients must not have received radiation therapy (including radiofrequency ablation) within 4 weeks before the first dose of the study drug. However, a single fraction of radiotherapy for palliation confined to one field is permitted within 1 week prior to Day 1 of treatment.
* Stereotactic Body Radiation Therapy: Patients must not have received this therapy within 2 weeks before the first dose of the study drug.
* Chemoembolization or Radioembolization: Patients must not have received these treatments within 4 weeks before the first dose of the study drug.
* Concomitant Medication:

* CYP3A4/5 Inducers or Inhibitors: Patients must not take strong CYP3A4/5 inducers or inhibitors (except enzalutamide in Cohort M8) within 7 days or 5 times the reported half-life of the CYP3A4/5 inhibitor or inducer (whichever is longer) prior to the first dose of the study drug and for the duration of the study.
3. Other Exclusions

* General Exclusions:

* Pregnancy and Breastfeeding: Patients who are breastfeeding, pregnant (as confirmed by a serum β-hCG pregnancy test within 72 hours prior to the first dose of the study drug), or planning to conceive or father children during the trial and for 183 days after the last dose of the study drug are excluded. Women of nonchildbearing potential (post-menopausal for more than 1 year or surgically sterilized) do not require a serum pregnancy test. A highly sensitive urine test can be used if a serum test is not appropriate. Female patients with false-positive β-hCG values may be enrolled with written consent from the Sponsor's Medical Monitor after pregnancy has been excluded.
* Compliance: Patients who are unwilling or unable to comply with the study protocol or requirements are excluded.
* Additional Exclusions for Cohort M6 (mCRPC) Only:

* Bone-only Disease: Patients with bone-only disease without nodal disease and no evidence of visceral spread are excluded.
* Structurally Unstable Bone Lesions: Patients with bone lesions that are structurally unstable and concerning for impending fracture are excluded.
* Herbal Products: Patients using herbal products that may decrease prostate-specific antigen (PSA) levels within 4 weeks prior to Day 1 of treatment and during the study are excluded.
* Prostate Cancer Treatments: Patients who have received the following treatments for prostate cancer within the specified timeframes prior to Day 1 of treatment are excluded:

1. First-generation androgen receptor antagonists (e.g., bicalutamide, nilutamide, flutamide) within 4 weeks.
2. 5α reductase inhibitors, ketoconazole, estrogens (including diethylstilbestrol), or progesterones within 2 weeks.
* Planned Palliative Procedures: Patients with planned palliative procedures for alleviation of bone pain, such as radiation therapy or surgery, are excluded.
4. Additional Exclusion Criteria for Cohort M8 (DZR123 and Enzalutamide Combination in mCRPC) only:

* Biochemical recurrence/prostate-specific antigen (PSA)-only disease.
* Prior Enzalutamide Treatment:

* For M8 Part 1: Patients who have received prior enzalutamide.
* For M8 Part 2: Patients who have received prior enzalutamide, apalutamide, darolutamide, or any other investigational androgen receptor pathway inhibitor (ARPi).
* Herbal Products: Use of herbal products that may decrease PSA levels within 4 weeks prior to Day 1 of treatment and during the study.
* Planned Palliative Procedures: Planned palliative procedures for alleviation of bone pain, such as radiation therapy or surgery.
* Investigational Agents: Treatment with any investigational agent within 4 weeks before Day 1 of M8 Part 1 or M8 Part 2.
* Bone Marrow Irradiation: Prior irradiation to more than 25% of the bone marrow.
* Gastrointestinal Conditions: Active inflammatory gastrointestinal disease, chronic diarrhea, known diverticular disease, or previous gastric resection or lap band surgery. Gastroesophageal reflux disease under treatment with proton pump inhibitors is allowed.
* Seizure History: History of seizure, loss of consciousness, or transient ischemic attack within 12 months of study entry, or any condition that may predispose to seizure (e.g., stroke, brain arteriovenous malformation, head trauma, underlying brain injury).

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