ForPatients
by Roche

Prostate Cancer

A clinical trial to compare the safety and effectiveness of ipatasertib plus atezolizumab and docetaxel in people with metastatic prostate cancer

A Study Evaluating The Safety, Efficacy and Pharmacokinetics Of Ipatasertib In Combination With Atezolizumab And Docetaxel In Metastatic Castration-Resistant Prostate Cancer (mCRPC).

Trial Status	Trial Runs In	Trial Identifier
Terminated	4 Countries	NCT04404140 2019-004591-19 CO41792

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase Ib, Open-Label, Multicenter Study Evaluating The Safety, Efficacy and Pharmacokinetics Of Ipatasertib In Combination With Atezolizumab And Docetaxel In Metastatic Castration-Resistant Prostate Cancer.

Trial Summary:

A study evaluating the safety, preliminary efficacy and pharmacokinetics of ipatasertib in combination with atezolizumab and docetaxel in participants with mCRPC previously treated with second-generation AR (Androgen Receptor)-targeted therapy. The study consists of two parts: [1] Part A: Safety run-in cohort of approximately 12 participants; [2] Part B: Expansion cohort of approximately 38 participants. All participants in this study will continue to be treated until progression of disease, loss of clinical benefit, unacceptable toxicity or withdrawal of consent.

Hoffmann-La Roche
Sponsor

Phase 1
Phase

NCT04404140 2019-004591-19 CO41792
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Male	#18 Years	No

How does the CO41792 clinical trial work?

This clinical trial is recruiting people who have a type of disease called prostate cancer that has spread to other parts of the body (known as metastatic) and who no longer benefit from standard treatments aiming to reduce testosterone levels in your body (known as castrate resistant).

The purpose of this clinical trial is to evaluate the effects, positive or negative, of ipatasertib plus atezolizumab and docetaxel in patients with metastatic castrate resistant prostate cancer.

How do I take part in this clinical trial? To be able to take part in this clinical trial, you must have been diagnosed with metastatic prostate cancer that has not got better after being treated with at least one type of medication called ‘androgen-receptor targeted therapy’.

You must not have received any recent chemotherapy for your metastatic prostate cancer, or any other previous treatments having the same “target” than those tested in this study. Your doctor will be able to give you more information on this.

If you think this clinical trial may be suitable for you and you would like to take part, please talk to your doctor. If your doctor thinks that you might be able to take part in this clinical trial, he/she may refer you to the closest clinical trial doctor. They will give you all the information you need to make your decision about taking part in the clinical trial. You can also find the clinical trial locations on this page.

You will have some further tests to make sure you will be able to take the treatments given in this clinical trial. Some of these tests or procedures may be part of your regular medical care. They may be done even if you do not take part in the clinical trial. If you have had some of the tests recently, they may not need to be done again.

Before starting the clinical trial, you will be told about any risks and benefits of taking part in the trial. You will also be told what other treatments are available so that you may decide if you still want to take part.

While taking part in the clinical trial, you will need to either not have heterosexual intercourse or take contraceptive measures for safety reasons, and you must also agree not to donate sperm.

What treatment will I be given if I join this clinical trial? This study will be done in two parts: Part A first followed by Part B. Which part you are entered into will depend on when you join the trial and then on the extent and prior treatment of your cancer.

The treatments in this clinical trial will be given in rounds or ‘cycles’, each lasting for 3 weeks (21 days).

Part A: Safety run-in (approximately 12 patients)

- Ipatasertib given as a tablet to take by mouth every day for 14 days, then stopped for 7 days
- Atezolizumab given through a drip as an infusion into the vein once every 3 weeks
- Docetaxel given through a drip as an infusion into the vein once every 3 weeks for up to 10 rounds of treatment (approximately 7 months).

After you have completed up to 10 rounds of docetaxel, your treatment will continue with ipatasertib and atezolizumab.

Part B: Expansion (approximately 38 patients)

If patients in Part A are able to take the treatments without any serious side effects, more people will be included in the trial. Patients in Part B will receive the same treatment as patients in Part A.

How often will I be seen in follow-up appointments and for how long? You will be given the clinical trial treatment for as long as it can help you. During your treatment visits your clinical trial doctor will also carry out scans and other medical assessments to see how your cancer is responding and any side effects that you may be having.

You are free to stop this treatment at any time. After you have finished treatment, your clinical trial doctor will contact you via telephone or through clinic visits approximately every 3 months (as long as you agree to it). These follow-up appointments will check for any side effects from the clinical trial and see how your cancer is responding to any other treatments you may receive after the clinical trial has finished.

What happens if I am unable to take part in this clinical trial? If this clinical trial is not suitable for you, you will not be able to take part. Your doctor may suggest other clinical trials that you may be able to take part in or other treatments that you can be given. You will not lose access to any of your regular care.

For more information about this clinical trial see the For Expert tab on the specific ForPatients page or follow this link to ClinicalTrials.gov

Trial-identifier: NCT04404140

Inclusion Criteria:

- Ability to comply with the study protocol.
- Adenocarcinoma of the prostate without small-cell or neuroendocrine features.

- Metastatic disease that cannot be treated with curative intent.
- Surgical or medical castration with testosterone serum level < 50 ng/dL (1.7 nM).
- For participants treated with luteinizing hormone-releasing hormone analogs, initiation therapy >= 4 weeks prior to the first dose of study treatment and continued therapy throughout study treatment.
- Progression of Prostate Cancer.
- Receipt of at least one prior line of second generation AR-targeted therapy.
- For participants in Part A of study: measurable visceral disease or measurable extrapelvic adenopathy per RECIST v1.1.
- For participants in Part B of study: either measurable visceral disease or measurable extrapelvic adenopathy by RECIST v1.1 or bone lesions by bone scan, or both.
- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1.
- Life expectancy of >= 3 months.
- Ability to swallow oral study drug.
- Adequate organ and bone marrow function.
- Resolved or stabilized toxicities resulting from previous therapy to Grade 1 (except for alopecia and neuropathy).
- For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures and agreement to refrain from donating sperm.

Exclusion Criteria:

- Prior treatment with an AKT, PI3K, or mTOR inhibitor.
- Prior treatment with radium or other therapeutic radiopharmaceuticals for prostate cancer.
- Prior therapy with an anti-PD-1, anti-PD-L1, anti-PD-L2 agent or with an agent directed to another stimulatory or co-inhibitory T-cell receptor (e.g., CTLA-4, OX-40, CD137).
- Prior treatment with docetaxel or another chemotherapy agent for mCRPC.
- Treatment with investigational therapy within 14 days prior to initiation of study drug.
- History or known presence of central nervous system metastases including leptomeningeal carcinomatosis.
- Uncontrolled tumor-related pain.
- Symptomatic lesions (e.g., bone metastases or metastases causing nerve impingement) amenable to palliative radiotherapy should be treated prior to enrollment.
- Asymptomatic metastatic lesions whose further growth would likely cause functional deficits or intractable pain (e.g., epidural metastasis that is not presently associated with spinal cord compression) should be considered for loco- regional therapy if appropriate prior to enrollment.
- Non-study-related minor surgical procedures =< 5 days or major (invasive) surgical procedure =< 28 days prior to the first dose of study treatment.
- Active Hepatitis B and C infection (HBV/HCV).
- Known HIV infection.
- Uncontrolled pleural effusion, pericardial effusion, or ascites.
- Illicit drug or alcohol abuse within 12 months prior to screening, in the investigator's judgment.
- Malabsorption syndrome or other condition that would interfere with enteral absorption.
- Serious infection requiring antibiotics within 14 days prior to the first dose of study treatment.
- Any serious medical condition or abnormality in clinical laboratory tests that, in the investigator's judgment, precludes the participant's safe participation in and completion of the study.
- History of another malignancy within 5 years prior to enrollment.
- History of clinically significant cardiovascular dysfunction.
- Presence of any other condition, metabolic dysfunction, physical examination finding, or laboratory finding that may increase the risk associated with study participation or may interfere with the interpretation of study results and in the opinion of the investigator, would make the participant inappropriate for study entry.

Ipatasertib-Specific Exclusion Criteria:

- Type 1 or Type 2 diabetes mellitus requiring insulin at study entry.
- History of inflammatory bowel disease (e.g., Crohn disease and ulcerative colitis) or active bowel inflammation (e.g., diverticulitis).
- Grade >= 2 uncontrolled or untreated hypercholesterolemia or hypertriglyceridemia.
- Treatment with strong CYP3A inhibitor or strong CYP3A inducer within 2 weeks or 5 drug-elimination half-lives of this treatment (whichever is longer) prior to initiation of study drug.

Atezolizumab-Specific Exclusion Criteria:

- Active or history of autoimmune disease or immune deficiency.
- History of idiopathic pulmonary fibrosis, organizing pneumonia (e.g., bronchiolitis obliterans), drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis on screening chest computed tomography (CT) scan.
- Prior allogeneic stem cell or solid organ transplantation.
- Treatment with a live, attenuated vaccine within 4 weeks prior to initiation of study treatment, or anticipation of need for such a vaccine during treatment with atezolizumab or within 5 months after the last dose of atezolizumab.
- History of severe allergic anaphylactic reactions to chimeric or humanized antibodies or fusion proteins.
- Known hypersensitivity to Chinese hamster ovary cell products or recombinant human antibodies.
- Treatment with systemic immunostimulatory agents within 4 weeks or 5 drug-elimination half-lives of the drug (whichever is longer) prior to initiation of study treatment.
- Need for chronic corticosteroid therapy of >10 mg of prednisone per day or an equivalent dose of other anti-inflammatory corticosteroids or immunosuppressants for a chronic disease.
- Treatment with systemic immunosuppressive medication within 2 weeks prior to initiation of study treatment, or anticipation of need for systemic immunosuppressive medication during the course of the study.

Docetaxel-Specific Exclusion Criteria:

- Known hypersensitivity or contraindication to any component of docetaxel, including its excipient polysorbate 80.
- Grade >= 2 peripheral neuropathy.