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 source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

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	Phase 1
Sponsor	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

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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)

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- 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

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