A Phase 2 Open-label Extension Study for Subjects with Prostate Cancer Who Previously Participated in an Enzalutamide Clinical Study

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This study has been transitioned to CTIS with ID 2023-510298-33-00 check the CTIS register for the current data. The objective of the study is to collect long term safety data in subjects who are continuing to derive clinical benefit from treatment...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON53607

Source
ToetsingOnline

Brief title
9785-CL-0123

Condition

- Other condition
- Metastases

Synonym
prostate cancer

Health condition

prostate cancer metastatic

Research involving
Human

Sponsors and support

Primary sponsor: Astellas Pharma Global Development, Inc.
Source(s) of monetary or material Support: Astellas Pharma Global Development;Inc. (APGD)

Intervention

Keyword: Enzalutamide, Open-label, Phase 2, Prostate Cancer

Outcome measures

Primary outcome

The objective of the study is to collect long term safety data in subjects who are continuing to derive clinical benefit from treatment with Enzalutamide (as assessed by the investigator) from their participation in an enzalutamide clinical study sponsored by Astellas or Medivation, Inc., a wholly owned subsidiary of Pfizer Inc. (Medivation/Pfizer) which has completed, at a minimum, the primary analysis or the study specified evaluation period.

Subjects should continue on the treatment regimen that they were receiving in the study they are enrolling from until any of the discontinuation criteria are met as outlined below. Dose changes of any of the prior therapies subjects were receiving on the previous protocol are allowed after medical monitor approval: monotherapy with enzalutamide or any dose change of the combination compound and background therapy. If enzalutamide is discontinued from a combination therapy, subject is to be taken off the study.

Secondary outcome

N/A

Study description

Background summary

Enzalutamide is a drug that is used to treat prostate cancer.

Enzalutamide blocks the action of the androgen receptor (AR) which is a cell receptor. Cell receptors are a type of protein that acts like locks on the surface of a cell that cause further chemical reaction inside of a cell. Sometimes in cancer, there are too many of these receptors compared to normal cells or these reactions happen more often than normal and lead to tumor cell growth.
Blocking of the androgen receptor has been important in prostate cancer to delay tumors from growing.

Study objective

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Study design

This is a multicenter, international, open-label extension study for subjects who are currently enrolled in a clinical trial receiving enzalutamide for treatment of their prostate cancer and who are continuing to derive clinical benefit at the termination of that trial, based on the assessment of the investigator. The investigator may proceed to roll-over a study subjects as long as subjects meet all entry criteria and if it is considered the best option for the subjects. Subjects must continue on the treatment regimen that they were receiving in the prior study. Dose changes of any of the prior therapies subjects were receiving on the previous protocol are allowed after medical monitor approval: monotherapy with enzalutamide or any dose change of the combination compound and background therapy.
Upon Institutional Review Board (IRB)/ Independent Ethics Committee (IEC) approval of the protocol, the subject will be asked for consent for this study

and all required procedures will be completed. The day 1 visit for this study should coincide with the last treatment visit for the study the subject will be enrolling from (<= 7 days post last visit of parent study). The subject will be instructed to return all study medication from the parent study at the final visit, and if eligible, will receive enzalutamide for this study on day 1.
The subjects will be followed according to the local institution*s standard of care and will be required to return to the institution every 24 weeks (± 7 days) to review adverse events (AEs), collect concomitant medications and, confirm that no discontinuation criteria are met. At each visit and at every 12 weeks (IP only visit) subjects are to return all dispensed study drug and to receive more study drug if applicable.
Telemedicine visits may be allowed due to specific circumstances. For visits done via telemedicine, delivery of further IP can be arranged with direct to subject shipment services.
The study subjects will continue to receive treatment until any of the discontinuation criteria are met. An end of study visit will be performed 30 days (±7 days) after the last dose of enzalutamide or prior to the initiation of another systemic anticancer therapy, whichever occurs first.

Intervention

Subjects will receive 160 mg (4 capsules) of enzalutamide orally once daily at the same time each day.

Subjects who experience a grade 3 or higher toxicity that is attributed to the study drug and cannot be ameliorated by the use of adequate medical intervention and/or dose reduction may interrupt study drug treatment for 1 week or until the toxicity grade improves to grade 2 or lower in severity. Study drug may be restarted at the subject*s initial dose at Day 1 or at a reduced dose (i.e., 120 mg or 80 mg/day) in consultation with the Medical Monitor. If co-administration of strong CYP2C8 inhibitor is discontinued, the enzalutamide dose should return to the dose used prior to initiation of the strong CYP2C8 inhibitor.

Study burden and risks

Enzalutamide may help with cancer prostate regression, but it is not certain. Participation may provide new information which may benefit cancer prostate patients in the future. It is hoped that information gained in this study will aid in the understanding of cancer and help in the development of new approaches to its treatment.

Disadvantages of participation in the study may be:
• possible side effects/complications of your prostate cancer;

Contacts

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. IRB/IEC approved written Informed Consent and privacy language as per national regulations [e.g., Health Insurance Portability and Accountability Act authorization for the United States sites] must be obtained from the subject prior to any study-related procedures.

2. Subject must currently be receiving enzalutamide for prostate cancer in a study sponsored by Astellas or Medivation/Pfizer and based on the investigator*s assessment, benefit from continued treatment. Subjects participating in investigator-initiated trials are not eligible.

3. Subjects are able to continue on the treatment regimen that they were receiving in the prior study. If in the investigator*s assessment a change is

needed to the subject*s regimen approval (e.g., dose change in androgen deprivation therapy (ADT) or dropping of a combination therapy) approval from a medical monitor is required prior to enrollment.

4. Subject is able to swallow enzalutamide capsules and comply with study requirements.

5. Subject and his female partner who is of childbearing potential must continue to use 2 forms of birth control, of which 1 must be highly effective* and 1 must be a barrier method* throughout the study and for 3 months after final enzalutamide administration.
Two acceptable forms of birth control include:
* Condom (barrier method of contraception), AND
* In addition to a condom, 1 of the following acceptable forms of contraception is required:
* Established use of oral, injected or implanted hormonal methods of contraception * Placement of an intrauterine device or intrauterine system
* Tubal ligation
* Vasectomy or other surgical castration prior to initial screening.

6. Subject agrees to avoid sperm donation during the study and for at least 3 months after final enzalutamide administration.

7. Subject agrees not to participate in another interventional study while on treatment. Waivers to the inclusion criteria will NOT be allowed

Exclusion criteria

1. Subject met any of the discontinuation criteria or progressed on the current enzalutamide clinical study in which they are enrolling from.
2. Subject requires treatment with or plans to use either of the following:
* New systemic therapy for their cancer (palliative radiation therapy is allowed). The treatment with agents administered during previous studies which was stopped and then restarted during this study does not represent new treatment (e.g., ADT).
* Investigational therapy other than enzalutamide

3. Subject is currently participating in an investigator-initiated interventional trial and receiving enzalutamide.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-05-2023
Enrollment:	13
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Xtandi
Generic name:	Enzalutamide
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	12-04-2022
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	15-11-2022
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	09-12-2022
Application type:	Amendment

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	12-12-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	11-06-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	18-10-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	05-12-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-01-2024
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EU-CTR	CTIS2023-510298-33-00
EudraCT	EUCTR2016-001694-32-NL
ClinicalTrials.gov	NCT02960022
CCMO	NL80332.068.22