Summary of Results for Laypersons

What was the Study Called?

A Multicenter, Open-label, Single-arm, Study of Enzalutamide Re-Treatment in Metastatic Castration-Resistant Prostate Cancer, As First Treatment Post-Chemotherapy in Patients who Have Previously Received Enzalutamide in the Pre-Chemotherapy Setting

Why was this Study Needed?

Prostate cancer growth is dependent on male hormones or "androgens." An example of an androgen is testosterone. Enzalutamide (also known as MDV3100 and Xtandi®) is a medicine used to treat patients with prostate cancer. It blocks the effect of androgens. For a time, this stops or slows down the growth of prostate cancer and lowers the blood level of a protein produced by prostate cancer cells. That protein is called prostate specific antigen or "PSA" for short. Gonadotropin-releasing hormone (GnRH, a hormone produced in the brain that controls reproductive hormones) can also be used to block PSA.

Patients in this study had been previously treated with enzalutamide. The main question this study helped answer was if enzalutamide taken with a GnRH agonist (activator)\antagonist (blocker) would increase the length of time a patient lives with prostate cancer but their prostate cancer would not get worse. It was also important to find out what unwanted effects these patients had from enzalutamide.

This study took place at 2 clinics in the United States. The study started in October 2015 and was stopped by the sponsor early, in March 2017, because not enough patients agreed to participate in the study. The sponsor (Astellas) reviewed all the study information and created a report of the results. This is a summary of that report.

What Kind of Study was This and Who Took Part in it?

This was an "open-label" study. This means that all patients knew that they took enzalutamide.

Men aged 18 years or older could take part in the study if:

- They had prostate cancer that had spread to a different part of the body.
- They had previously been treated with enzalutamide for at least 8 months followed by at least 4 cycles of chemotherapy.
- They were receiving therapies to stop or slow androgen with GnRH or had surgery to remove both testes. They had to have a blood testosterone level ≤1.73 nmol/L at study start.

Patients could not take part in this study if:

- They had prostate cancer with neuroendocrine/small cell features.
- They were taking treatments to stop or slow the development of tumors.
- They received radiation at least 2 weeks before the beginning of the study.
- They had a history of convulsions or seizures or cardiovascular disease.

Patients were seen at the clinic every 4 weeks until week 25. After week 25, patients were seen in the clinic every 12 weeks. During the study, the study doctor did a check-up of the patients at several study visits. At visit 1, patients were checked to see if they could be in the study. Patients who could be in the study took enzalutamide 160 mg (four 40-mg capsules) by mouth once a day until the patients' prostate cancer worsens. Patients also took either a GnRH agonist (activator)/antagonist (blocker) or had surgery to remove both testes. Blood samples were collected during the study to test the patients' level of PSA. At weeks 9, 17 and 25 (and every 12 weeks thereafter), patients had the following tests to look at their prostate cancer:

- CT (computed tomography) scan: a CT scan combines X-ray images from different angles to create pictures on a computer of slices of structures inside the body
- Magnetic resonance imaging (MRI) scan: an MRI scan uses a large magnet and radio waves to create pictures on a computer of structures inside the body.
- Bone scans: for a bone scan, a tiny amount of radioactive material is injected into a vein. The radioactive material is spread through the body and taken up by cells that are growing fast in the bones, such as cancer cells. These cells will emit radiation. After 3 to 4 hours, a camera slowly scans the body. It creates pictures on a computer to show how much radioactive material is taken up by the cancer cells in the bones.

Four (4) patients were in the study and took at least 1 dose of enzalutamide. Each patient discontinued the study before the sponsor (Astellas) stopped the study early.

	Number of Patients
Age Group Aged between 71 and 79 years	4
Clinic Location United States	4

What Were the Study Results?

The main question this study helped answer was if enzalutamide taken with a GnRH agonist (activator)\antagonist (blocker) would increase the length of time a patient lives with prostate cancer but their prostate cancer would not get worse. Because of the low number of patients who took part in this study the study question could not be answered. This is the summary of what was learned during the study:

- One patient's prostate cancer was stable for 173 days (with 175 days of treatment).
- After 79 days of treatment, one patient's prostate cancer worsened in 57 days.
- Another patient's prostate cancer was stable for 52 days (with 85 days of treatment)
- One patient's prostate cancer did not worsen for 52 days (with 71 days of treatment).

What Adverse Reactions did Patients Have?

A lot of research is needed to know whether a medicine causes a medical problem. So when new medicines are being studied researchers keep track of all medical problems that patients have while they are in the study. These medical problems are called "adverse events" and are

recorded whether or not they might be caused by the treatment taken. An "adverse reaction" is any medical problem or "adverse event" that is judged by the study doctor to be possibly caused by a medicine or treatment used in the study.

Three (3) patients who took at least 1 dose of enzalutamide each had 1 or more adverse reactions. The table below shows the most common adverse reactions experienced by these patients.

Adverse Reaction	**Number of Patients (out of 4 patients)**
Any adverse reaction	3
Fatigue or tiredness	2
Feeling hot for a brief moment	1
Decreased blood level of potassium	1
Trouble with memory	1
Swelling of tissues due to excessive collection of lymph (the clear fluid that is collected from tissues throughout the body) due to a blockage in the lymphatic vessels	1
Nausea or the urge to vomit	1
Loss of appetite	1

An adverse reaction is considered "serious" when it is life-threatening, causes lasting problems or needs hospital care.

There were no serious adverse reactions in this study.

Where Can I Learn More About This Study?

The information in this document reflects the information available as of November 2017.

Astellas may perform additional studies to better understand enzalutamide.

This summary of the clinical study results is available online at http://www.astellasclinicalstudy results.com.

Please remember that researchers look at the results of many studies to find out how well medicines work and which adverse reactions they might cause. If you have questions about enzalutamide, please discuss these with your doctor.

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