Summary of Results for Laypersons

What was the Study Called?

A Phase 2, Multicenter, Single-arm, Open-label Study to Monitor the Safety of Enzalutamide in Patients with Progressive Castration-resistant Prostate Cancer Previously Treated with Docetaxel-based Chemotherapy

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. Docetaxel (also known as Taxotere) is a chemotherapy medicine that is also used to treat patients with prostate cancer. It may be used by itself or along with other chemotherapy medications.

Prostate cancer that keeps growing even when the amount of testosterone in the body is reduced to very low levels is called castration-resistant prostate cancers (CRPC). In a previously completed clinical study, patients with CRPC who were previously treated with docetaxel lived longer when they were treated with enzalutamide. That study was conducted in many countries, but did not include Eastern European patients. The purpose of this study was to assess the safety of treatment with enzalutamide in Eastern European patients who had CRPC and were previously treated with docetaxel. It was important to find out what unwanted effects these patients had from enzalutamide.

This study took place at 4 clinics in Russia and Georgia. The study started in September 2014 and ended in May 2017. When the study ended, 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 could take part in the study if:

- Their doctor determined that they had prostate cancer. Their prostate cancer had spread from the prostate to other places in the body.
- They were taking hormonal therapy that blocks the effect of androgens and were planning to continue this therapy throughout the study or they had been castrated.
- They had at least 1 prior chemotherapy regimen that included docetaxel.
- Their cancer had not spread to the brain.

Men could not take part in this study if:

- They had a condition that the study doctor thought would make it hard for them to take part in the study or their condition would make it hard to evaluate their study results.
- They had abnormal hematology laboratory tests. Hematology laboratory tests examine blood formation and blood disorders. Patients could not receive growth factors or blood transfusions 7 days prior to the start of the study.
- They had abnormal liver or kidney function.
- They received anti-androgen therapy, chemotherapy or any other therapy for prostate cancer 4 weeks prior to the start of the study.
- They had a history of convulsion or seizures.
- They had a history of loss of consciousness or transient ischemic attack (a stroke that comes and goes quickly [a mini stroke] with no lasting effects. That can be a warning of future stroke) 12 months prior to the start of the study.

Before the start of study treatment, 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. Patients had study visits on day 1, week 5, week 13 and every 12 weeks thereafter. The study doctor did a check-up of the patients at every study visit and blood samples for laboratory tests were collected at each visit. After Astellas had ended the study, the study doctor determined if the patients would still benefit from the enzalutamide treatment. If so, these patients could continue enzalutamide treatment in a new extension study (9785-CL-0123).

Thirty (30) patients were in the study and took at least 1 dose of enzalutamide.

	Number of Patients
Age Group	
Aged between 59 and 80 years	30
Clinic Location	
Russia	20
Georgia	10

What Were the Study Results?

The purpose of this study was to assess the safety of treatment with enzalutamide in Eastern European patients who had CRPC and were previously treated with docetaxel. The median (a middle value in a sorted list of numbers) number of months that patients took enzalutamide in this study was about 9 months (271 days). The safety results in this study were consistent with the previous enzalutamide studies.

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.

Seven (7) patients who took at least 1 dose of enzalutamide each had 1 or more adverse reactions. The table below shows the adverse reactions experienced by these patients.

Adverse Reaction	**Number of Patients (out of 30 patients)**
Any adverse reaction	7 (23.3%)
Early electrical impulse in the heart usually originating in an area located above the ventricles	1 (3.3%)
Weakness, lack of energy, or loss of strength	2 (6.7%)
Fatigue or tiredness	3 (10.0%)
Dizziness (or sensation of lightheadedness, unsteadiness or giddiness)	1 (3.3%)
Headache or head pain	1 (3.3%)
Difficulty sleeping or falling asleep	1 (3.3%)
Frequent urge to urinate during the day	1 (3.3%)
Hair loss	1 (3.3%)

An adverse reaction is considered "serious" when it is life-threatening, causes lasting problems or needs hospital care. There were no serious adverse reactions during this study.

Four patients died during the study. Each of these deaths was not related to the study medicine. Three patients experienced adverse reactions of disease progression (worsening, growth or spread of the disease). One patient experienced adverse reactions of liver, lung and heart failure (the inability of the heart to adequately pump blood to supply oxygen to the body).

Where Can I Learn More About This Study?

The information in this document reflects the information available as of November 2017. This summary of the clinical study results is available online at http://www.astellasclinicalstudyresults.com.

Astellas may perform additional studies to better understand enzalutamide.

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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