Summary of Results for Laypersons

What was the Study Called?

A Phase 2 Open-label Extension Study to Assess the Safety of Continued Administration of MDV3100 in Subjects with Prostate Cancer Who Showed Benefit from Prior Exposure to MDV3100

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.

This study was an extension of several previous enzalutamide studies. The purpose of this study was to allow patients who were in the previous enzalutamide studies to benefit from receiving continued treatment with enzalutamide per the study doctor. The patients who participated in studies 9785-CL-0003, 9785-CL-0007 and 9785-CL-0406 could be enrolled in this study. It was also important to find out what unwanted effects these patients had from enzalutamide.

This study took place at 7 clinics in Moldova, South Africa and the United States. The study started in November 2011 and ended in April 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 aged 18 years or older could take part in the study if:

- They had completed a prior study with enzalutamide and would continue to benefit from enzalutamide per the study doctor.
- They did not have any abnormal clinical tests (e.g., physical exams, laboratory data or vital signs).

Patients could not take part in this study if:

- 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. They can be a warning of future stroke) prior to the study.

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 for up to 85 weeks. Blood samples were collected at each visit during the study. Patients could continue taking the study medicine if the study doctor determined that they would benefit from it. After Astellas had ended the study, the study doctor determined if they would still benefit from the treatment. If so, these patients could continue enzalutamide treatment in a new extension study.

Fifty-two (52) patients were in the study and took at least 1 dose of enzalutamide.

	Number of Patients
Age Group	
Aged between 54 and 88 years	52
Clinic Location	
Moldova	13
South Africa	13
United States	26

What Were the Study Results?

This study was an extension of several previous enzalutamide studies. The purpose of this study was to allow patients who were in the previous enzalutamide studies to benefit from receiving continued treatment with enzalutamide per the study doctor. The median (a middle value in a sorted list of numbers) number of months in this study patients took enzalutamide was about 13 months (392 days).

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.

Twenty-seven (27) 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 52 patients)**
Any adverse reaction	27 (51.9%)
Fatigue or tiredness	9 (17.3%)
Feeling hot for a brief moment	6 (11.5%)
Diarrhea	3 (5.8%)
Decreased blood level of phosphate	3 (5.8%)
Muscle weakness	3 (5.8%)

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

Five patients experienced serious adverse reactions. The table below shows these serious adverse reactions.

Serious Adverse Reaction	**Number of Patients (out of 52 patients)**
Increased growth of cancer cells	2 (3.8%)
Sudden inflammation (swelling and redness) of the pancreas	1 (1.9%)
Bleeding in or from the rectum	1 (1.9%)
Stoppage of blood flow to your brain	1 (1.9%)
Slow and slurred speech resulting from a lack of control of the muscles used in speech	1 (1.9%)
Weakness of one entire side of the body	1 (1.9%)
Severe increase in blood pressure that can lead to a stroke	1 (1.9%)

Five patients died during the study. The death of 2 patients could have been related to the study medicine. These 2 patients experienced serious adverse reactions of an increased growth of cancer cells.

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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