

## Summary of Results for Laypersons

Astellas is grateful to the patients who took part in this clinical study. Thank you.

### What was the Study Called?

A Phase 2 Study Determining Safety and Tolerability of Enzalutamide (Formerly MDV3100) in Combination With Abiraterone Acetate in Bone Metastatic Castration-resistant Prostate Cancer Patients

### Why was this Study Needed?

Prostate cancer growth is dependent on male hormones or “androgens.” An example of an androgen is testosterone. 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 cancer (CRPC). Enzalutamide (also known as MDV3100 and Xtandi®) is a medicine used to treat patients with prostate cancer. It blocks the effect of androgens. Abiraterone acetate is a medicine that is also used to treat patients with prostate cancer. It blocks androgens. Prednisone is used to help prevent unwanted effects that abiraterone acetate may cause. The medicines alone (enzalutamide or abiraterone acetate plus prednisone) stop or slow down the growth of prostate cancer for a time. There was a need to study the medicines together as a treatment for prostate cancer.

This study was conducted in patients who had CRPC. Patients took a combination of enzalutamide, abiraterone acetate and prednisone. This study looked at how safe it was for patients with CRPC to take enzalutamide together with abiraterone acetate and prednisone. It was also important to find out what unwanted effects these patients had from the study medicines.

The study started in July 2012 and ended in January 2018. When the study ended, the sponsor of this study (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 the patients and study doctors knew the study medicines they took (enzalutamide, abiraterone acetate and prednisone).

This study included men who had prostate cancer that had spread from the prostate to the bone. During the study, they were taking hormone treatment that blocks the effect of androgens. Or they had been castrated. Their testosterone level was  $\leq 50$  ng/dL. (“ng/dL” is a unit that measures the amount of the material in the blood. For example, a testosterone blood level of 50 ng/dL means that there is 50 ng of testosterone in 1 dL of blood.) They were active or could perform light daily activities. They were expected to live for at least 6 months.

During the study, the study doctor did a check-up of the patients at several study visits. At the first visit, patients were checked to see if they could be in the study. Patients who could

be in the study took the study medicines by mouth: 160 mg (four 40-mg capsules) of enzalutamide once a day, 1000 mg (four 250-mg tablets) of abiraterone once a day and 5 mg (1 tablet) of prednisone twice a day.

The patients could take the study medicines until their cancer got worse, they had unwanted effects they could not tolerate, they asked to stop treatment or they died.

This study took place at 1 clinic in the US. 60 patients were in the study and took at least 1 dose of the 3 study medicines (enzalutamide, abiraterone acetate and prednisone).

	<b>Number of Patients</b>
<b>Age Group</b>	
Aged less than 55 years	7
Aged 55 to less than 65 years	19
Aged 65 to less than 75 years	25
Aged 75 years or older	9
<b>Sex</b>	
Men	60
<b>Clinic Location</b>	
US	60

### What Were the Study Results?

This study looked at how safe it was for patients with CRPC to take enzalutamide together with abiraterone acetate and prednisone.

A lot of research is needed to know whether a medicine causes a medical problem. So when new medicines are being studied study doctors 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.

The mean (average) number of days that patients took all 3 study medicines was 527 days (1 year and 5.3 months).

The table below shows the most common adverse events experienced by patients who took at least 1 dose of all 3 study medicines.

<b>Adverse Event</b>	<b>Enzalutamide + Abiraterone Acetate + Prednisone (out of 60 patients)</b>
Any adverse event	60 (100%)
Increased blood sugar level	41 (81.7%)
Fatigue or tiredness	43 (71.7%)
Increased blood level of a liver or bone enzyme (alkaline phosphatase)	32 (53.3%)
Feeling hot for a brief moment	27 (45.0%)
Increased blood level of a liver enzyme (aspartate aminotransferase)	22 (36.7%)
Lack of enough red blood cells (anemia)	21 (35.0%)

## What Adverse Reactions did Patients Have?

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.

The table below shows the most common adverse reactions experienced by patients who took at least 1 dose of all 3 study medicines in this study.

Adverse Reaction	Enzalutamide + Abiraterone Acetate + Prednisone (out of 60 patients)		
	Enzalutamide- related	Abiraterone acetate-related	Prednisone- related
Any adverse reaction	56 (93.3%)	58 (96.7%)	16 (26.7%)
Fatigue or tiredness	35 (58.3%)	20 (33.3%)	1 (1.7%)
Feeling hot for a brief moment	23 (38.3%)	26 (43.3%)	0
High blood pressure	18 (30.0%)	14 (23.3%)	1 (1.7%)
Increased blood level of a liver enzyme (aspartate aminotransferase)	17 (28.3%)	17 (28.3%)	4 (6.7%)
Increased blood level of a liver enzyme (alanine aminotransferase)	15 (25.0%)	16 (26.7%)	3 (5.0%)

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

Two patients (3.3%, or 2 out of 60 patients) experienced serious adverse reactions (related to abiraterone acetate).

## Where Can I Learn More About This Study?

This document is a short summary of the main results from this study and reflects the information available as of November 2018. You can find this summary and more information about this study online at <http://www.astellasclinicalstudyresults.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. This summary only shows the results of this 1 study. Your doctor may help you understand more about the results of this study.

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