



# CLINICAL TRIAL RESULTS

This summary reports the results of only one study. Researchers must look at the results of many types of studies to understand if a study medicine works, how it works, and if it is safe to prescribe to patients. The results of this study might be different than the results of other studies that the researchers review.

**Sponsor:** Pfizer, Inc.

**Medicine(s) Studied:** Enzalutamide/PF-04998299 (formerly MDV3100)

**Protocol Number:** MDV3100-09 (C3431014)

**Dates of Trial:** 07 August 2012 to 17 January 2018

**Title of this Trial:** Safety and Efficacy Study of Enzalutamide Versus Bicalutamide in Men With Prostate Cancer (STRIVE)  
[STRIVE: A Multicenter Phase 2, Randomized, Double-Blind, Efficacy and Safety Study of Enzalutamide vs. Bicalutamide in Men With Prostate Cancer Who Have Failed Primary Androgen Deprivation Therapy]

**Date of this Report:** 7 May 2020

— *Thank You* —

Pfizer, the Sponsor, would like to thank you for your participation in this clinical trial and provide you a summary of results representing everyone who participated. If you have any questions about the study or results, please contact the doctor or staff at your study site.

## WHY WAS THIS STUDY DONE?

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Prostate cancer is the name for cancer that starts in the prostate, which is a small, walnut-sized gland that lies at the base of the bladder in men and is part of the male reproductive system.

Prostate cancer is a common cancer in men, and it is often a slow-growing cancer with few symptoms.

Enzalutamide is a prescription medicine that is approved to treat men with prostate cancer. Enzalutamide works by interfering with the connections between androgens (a type of hormone that plays a role in male traits and reproductivity) and androgen receptors (a protein in the body that attaches to androgens). This may help to slow the growth of prostate cancer.

The main goal of this study was to learn more about the use of enzalutamide in patients with prostate cancer that did not sufficiently improve after receiving treatment to block androgens. Researchers wanted to answer this research question:

- How long did patients survive without prostate cancer getting worse after receiving enzalutamide, compared to bicalutamide?

Bicalutamide is a medicine approved to treat men with prostate cancer.

## WHAT HAPPENED DURING THE STUDY?

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This study compared 2 groups of patients to find out how long patients would survive without prostate cancer getting worse after receiving enzalutamide, compared to bicalutamide. The study included patients who had prostate cancer that did not sufficiently improve after receiving treatment to block androgens. These patients had either mild prostate cancer symptoms or no prostate cancer symptoms when the study began.

Patients in this study were assigned to receive either enzalutamide or bicalutamide. The patients and researchers did not know who took enzalutamide and who took bicalutamide. This is known as a “blinded” study. Patients were assigned to each treatment group by chance alone. This is known as a “randomized” study. Putting

people into groups by chance helps make the groups more similar so they can be compared.

First, patients were checked by a study doctor to make sure they met the requirements to join the study. This was called the screening period.

During the treatment period, patients received the following treatments:

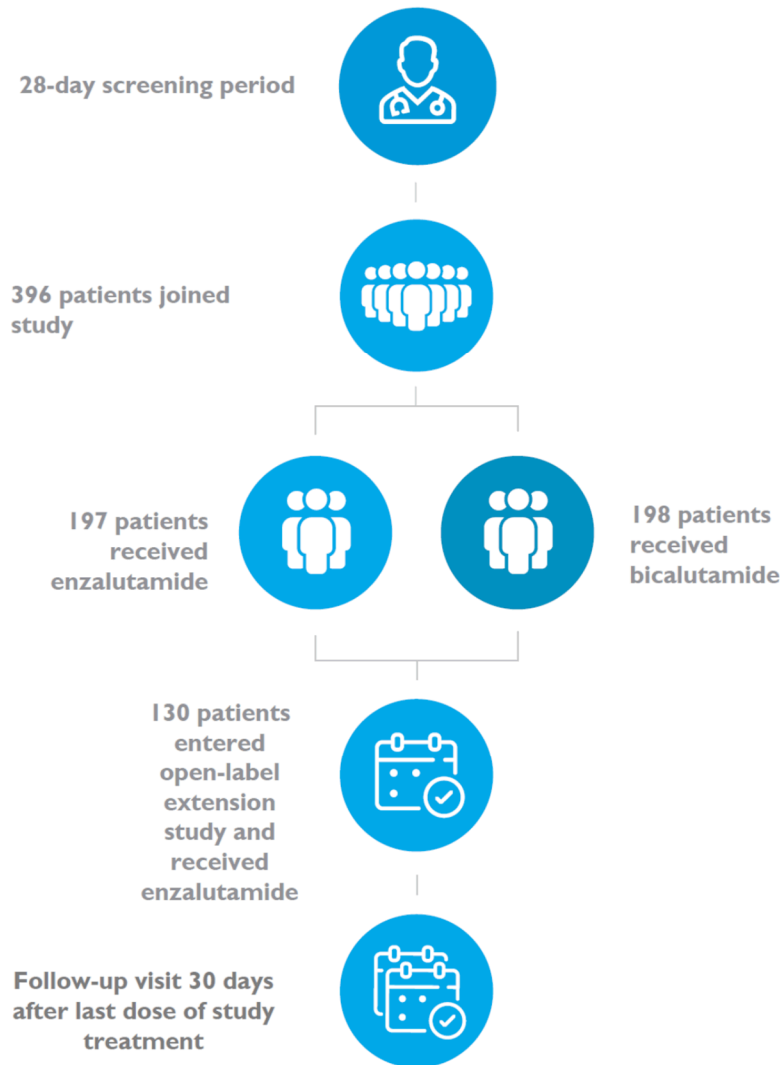
- Group 1: 197 patients received enzalutamide at a dose of 160 milligrams (mg), taken by mouth each day
- Group 2: 198 patients received bicalutamide at a dose of 50 mg, taken by mouth each day

Patients in both groups also received placebo pills. A placebo does not have any active medicine in it, but looks just like the medicine. The placebo pills were given so that both treatments would look the same, and the study would remain blinded.

During the treatment period, patients came to study visits at week 1, week 5, and week 13, then every 12 weeks thereafter. At the study visits, imaging tests were done and patients were checked by study doctors to determine if prostate cancer was getting worse. Patients were also asked about any medical problems they were having.

After researchers reviewed results from the treatment period, patients had the option to enter the “open-label extension” part of the study. During this part of the study, all patients received enzalutamide and came to study visits at week 1, week 5, week 17, and then every 16 weeks thereafter. “Open-label” means that the patients and researchers knew which medicine the patients were taking. Patients came to a follow-up visit 30 days after their last dose of study treatment.

The figure on the following page shows what happened during this study.



The amount of time that patients were in the study varied, but the entire study took more than 5 years to complete, including both the main part of the study and the open-label extension part of the study. The sponsor ran this study at 62 locations in the United States. It began 07 August 2012 and ended 17 January 2018. 396 men joined the study, and 395 men received study treatment. All patients were between the ages of 46 and 92.

Patients were to continue receiving study treatment until it was confirmed that their prostate cancer had gotten worse. Of the 396 patients who started the study, 145 patients (37%) were still receiving study treatment when the main part of the

study ended in February 2015. 251 patients (63%) stopped taking study treatment by their choice, because a doctor decided it was best for a patient to stop the study, because they had a medical problem, because prostate cancer got worse, or because they passed away. A total of 93 patients from the enzalutamide group and 37 patients from the bicalutamide group entered the open-label extension part of the study and received enzalutamide.

When the study ended in January 2018, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

## **WHAT WERE THE RESULTS OF THE STUDY?**

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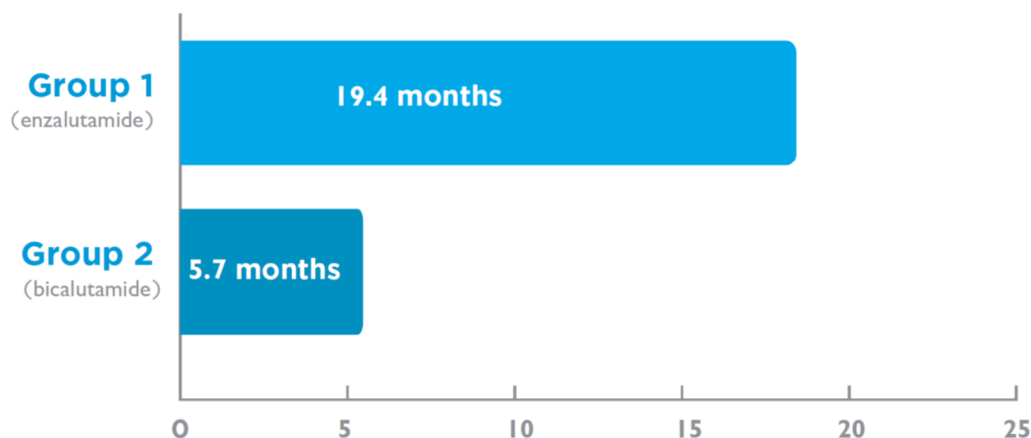
### **How long did patients survive without prostate cancer getting worse after receiving enzalutamide, compared to bicalutamide?**

To answer this question, the researchers looked at data gathered from the beginning of the study until the main part of the study ended in February 2015. They looked at the median length of time that patients survived without cancer getting worse after receiving study treatment. A “median” is the middle number in a group of numbers. So, researchers looked at the length of time that each patient survived without cancer getting worse, in order from highest to lowest. The median is the middle number, and patients would have the same chance of surviving a longer time or a shorter time than this number without cancer getting worse.

During this time, the median length of time that patients survived without cancer getting worse after receiving enzalutamide was 19.4 months, while the median length of time that patients survived without cancer getting worse after receiving bicalutamide was 5.7 months.

The researchers have determined that these results are clinically meaningful, and not likely based on chance. The figure on the following page shows these study results.

## Median Survival Time Without Cancer Getting Worse: Beginning of Study Until February 2015



This does not mean that everyone in this study had these results. Other studies may produce different results, as well. These are just some of the main findings of the study, and more information may be available at the websites listed at the end of this summary.

## WHAT MEDICAL PROBLEMS DID PATIENTS HAVE DURING THE STUDY?

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The researchers recorded any medical problems the participants had during the study. Participants could have had medical problems for reasons not related to the study (for example, caused by an underlying disease or by chance). Or, medical problems could also have been caused by a study treatment, or by another medicine the participant was taking. Sometimes the cause of a medical problem is unknown. By comparing medical problems across many treatment groups in many studies, doctors try to understand what the side effects of an experimental drug might be.

369 out of 395 (93%) patients who received study treatment had at least 1 medical problem. A total of 58 patients (15%) stopped taking study treatment because of medical problems. Out of the 37 patients who took bicalutamide during the main part of the study and switched to enzalutamide during the open-label extension part

of the study, 36 patients (97%) had at least 1 medical problem. 9 (24%) of these patients stopped taking study treatment because of medical problems. The most common medical problems are listed below.

### Most Common Medical Problems (Reported by More Than 10% of Patients)

Medical Problem	Enzalutamide (197 Patients treated)	Bicalutamide (198 Patients treated)	Bicalutamide During Main Study/ Enzalutamide During Open- Label Extension (37 Patients treated)
Feeling tired	83 (42%)	57 (29%)	10 (27%)
Joint pain	46 (23%)	29 (15%)	5 (14%)
Fall	42 (21%)	19 (10%)	8 (22%)
Back pain	41 (21%)	34 (17%)	3 (8%)
Nausea	38 (19%)	32 (16%)	9 (24%)
Hot flush	34 (17%)	20 (10%)	2 (5%)
Constipation	29 (15%)	33 (17%)	6 (16%)
Low appetite	28 (14%)	17 (9%)	6 (16%)
Diarrhea	27 (14%)	29 (15%)	9 (24%)
Feeling dizzy	27 (14%)	15 (8%)	6 (16%)
High blood pressure	26 (13%)	10 (5%)	5 (14%)
Low number of red blood cells	24 (12%)	21 (11%)	4 (11%)
Pain in hands or feet	23 (12%)	10 (5%)	1 (3%)
Difficulty sleeping	22 (11%)	9 (5%)	2 (5%)

Urinary tract infection	16 (8%)	23 (12%)	7 (19%)
Heartburn	10 (5%)	2 (1%)	6 (16%)
Heart failure	7 (4%)	5 (3%)	4 (11%)
Low blood pressure	6 (3%)	6 (3%)	4 (11%)

## WERE THERE ANY SERIOUS MEDICAL PROBLEMS?

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A medical problem is considered “serious” when it is life-threatening, needs hospital care, or causes lasting problems.

136 out of 395 patients (34%) had serious medical problems, including 76 patients (39%) in the enzalutamide group and 60 patients (30%) in the bicalutamide group. Out of the 37 patients who took bicalutamide during the main part of the study and switched to enzalutamide during the open-label extension part of the study, 16 patients (43%) had serious medical problems.

A total of 18 patients (5%) died during the study, including 11 patients (6%) in the enzalutamide group and 6 patients (3%) in the bicalutamide group. Out of the 37 patients who took bicalutamide during the main part of the study and switched to enzalutamide during the open-label extension part of the study, 1 patient (3%) died. 5 of the 18 deaths were due to prostate cancer progression, and 13 of these deaths were due to a medical problem.

## WHERE CAN I LEARN MORE ABOUT THIS STUDY?

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If you have questions about the results of your study, please speak with the doctor or staff at your study site.



The full scientific report of this study is available online at:

[www.clinicaltrials.gov](http://www.clinicaltrials.gov)

Use the study identifier **NCT01664923**

Clinical trials with enzalutamide are ongoing. Please remember that researchers look at the results of many studies to find out which medicines can work and are safe for patients.

Again, **thank you** for volunteering.  
We do research to try to find the  
best ways to help patients, and you  
helped us to do that!