



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: Xtandi (enzalutamide, formerly MDV3100)

Protocol Number: C3431012 (MDV3100-18)

Dates of Trial: 07 December 2015 to 03 May 2019

Title of this Trial: ¹⁸F-Sodium Fluoride PET/CT Bone Imaging in Patients With Castration-Resistant Prostate Cancer and Bone Metastases [A Phase 2, Open-Label, Single-Arm Study of ¹⁸F-Sodium Fluoride PET/CT Bone Imaging in Enzalutamide-Treated Chemotherapy-Naïve Patients With Bone-Metastatic Castration-Resistant Prostate Cancer]

Date of this Report: 24 January 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?

Prostate cancer is common in men and happens when the cells of the “prostate” start to grow out of control. The prostate is a gland that is part of the male reproductive system. Patients with prostate cancer are often treated with hormone therapy and/or “orchiectomy”. Orchiectomy is the surgical removal of 1 or both testicles (sometimes called castration). Even with hormone therapy and/or surgery, the cancer can come back. If this happens, it is called castration-resistant prostate cancer and hormone therapy, immunotherapy, radiotherapy, or chemotherapy may be given. Prostate cancer may also “metastasize” or spread to other areas of the body. Often new cancers will develop in the bone and these cancers are described as metastatic bone tumors.

One type of hormone therapy that can be given to patients with castration-resistant prostate cancer is Xtandi[®] (enzalutamide). This medicine can be used to treat metastatic as well as non-metastatic disease in many countries around the world, including the United States, Canada and Europe.

This study used ¹⁸F-sodium fluoride positron-emission tomography/computed tomography (¹⁸F-NaF PET-CT) to look at the effect of enzalutamide treatment on metastatic bone tumors in patients with castration-resistant prostate cancer. ¹⁸F-NaF PET-CT is an imaging test that can be used to see what is happening to a tumor and if the tumor is responding to treatment. Patients in this study were treated with enzalutamide and the researchers looked to see if the tumor was shrinking, staying the same, or getting bigger after treatment. If the tumor gets bigger, different treatment options may be needed.

WHAT HAPPENED DURING THE STUDY?

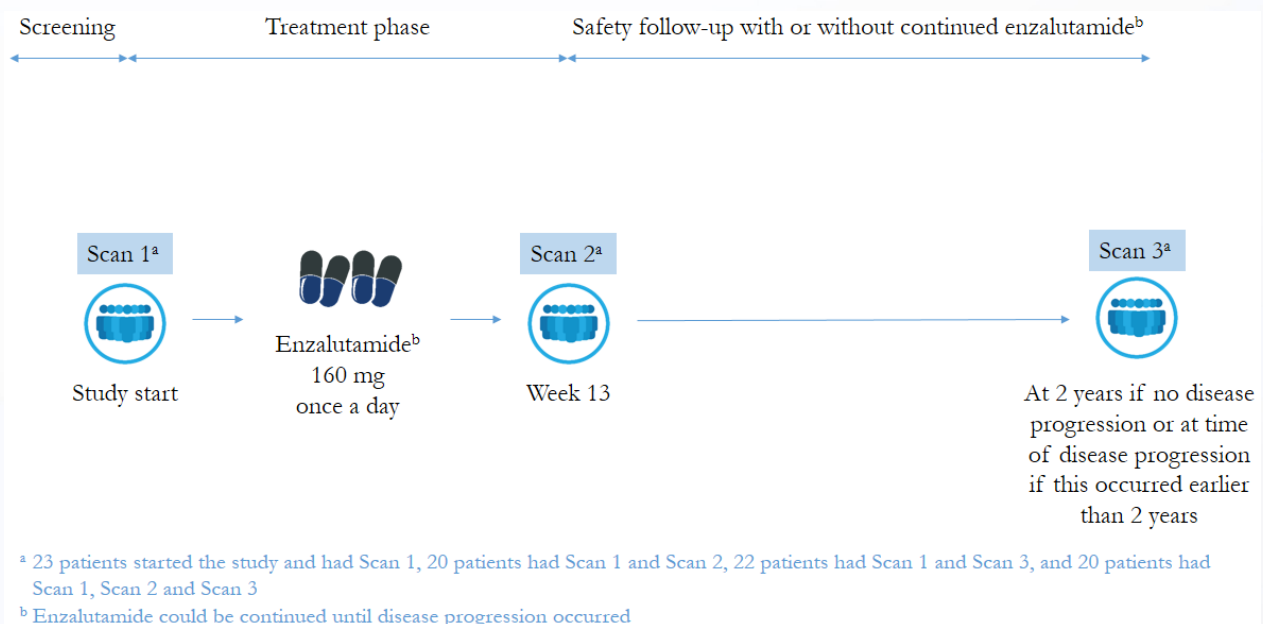
This study compared a single group of patients to find out if ¹⁸F-NaF PET-CT imaging could be used to look at treatment response in metastatic bone tumors in patients taking enzalutamide.

The study included patients who had castration-resistant prostate cancer with metastatic bone tumors and who were “chemotherapy naïve in this setting”. This

means that the patient must not have been previously treated with chemotherapy for their castration-resistant prostate cancer.

While patients were only in the study for up to 36 months, the entire study took 3 years and 5 months to complete. The Sponsor ran this study at 3 locations in the United States. It began on 07 December 2015 and ended 03 May 2019. A total of 23 men participated. All patients were between the ages of 51 and 93 years.

Patients were to be initially treated until Week 13 and have Scan 1 performed at screening and Scan 2 at Week 13. At the Week 13 visit, the doctor decided if the patient's enzalutamide treatment was to be stopped due to "disease progression", which means the cancer was getting worse, or if enzalutamide could be continued. Disease progression could be determined by looking at scans or from the patient's symptoms. If disease progression occurred either at Week 13 or after this time-point, the patient was removed from the study. If the patient was removed from the study after Week 13, Scan 3 was performed. Patients who remained in the study and were treated with enzalutamide beyond Week 13 were regularly monitored. In patients with no disease progression, the final Scan 3 was performed 2 years after the patient had first started treatment with enzalutamide. The doctor could also stop a patient's enzalutamide treatment during the study if the patient had medical problems that they could not tolerate like feeling too tired all the time or if their blood pressure was too high.



Of the 23 patients who started the study and had Scan 1, 20 patients had Scan 1 and Scan 2, 22 patients had Scan 1 and Scan 3, and 20 patients had all 3 scans. 16 patients left before the study was over by their choice or a doctor decided it was best for the patient to stop the study, 1 patient left because of medical problems, and 1 patient passed away. There were 5 patients who were transferred by their doctor to an extension study so they could continue enzalutamide treatment.

When the study ended in May 2019, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

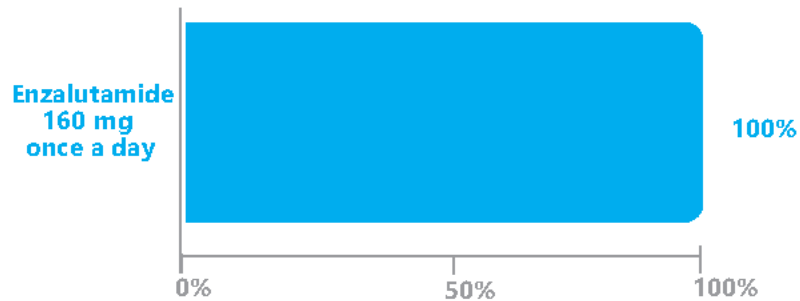
WHAT WERE THE RESULTS OF THE STUDY?

How many patients had 1 or more metastatic bone tumors that responded to enzalutamide treatment?

There were 22 patients with data from Scan 1 and Scan 3. All of these 22 patients (100%) had metastatic bone cancer that responded to enzalutamide treatment at Scan 3. Scan 3 was performed either at the time the patient's cancer had progressed or 2 years after the patient started enzalutamide treatment if their cancer had not progressed.

Based on these results, the researchers concluded that ^{18}F -NaF PET/CT imaging can be used to look at how metastatic bone tumors change with treatment and whether the tumor shrinks, stays the same or gets bigger.

Patients With Responding Bone Lesions at Scan 3



Other studies may produce different results to this study. 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?

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.

A total of 22 out of 23 patients (96%) in this study had at least 1 medical problem (see table). A total of 4 out of the 23 patients (17%) left the study because of medical problems. The most common medical problem reported was tiredness; 19 out of the 23 patients (83%) had this medical problem.

Most Common Medical Problems (Reported by More Than 20% of Patients)

Medical Problem	Enzalutamide 160 mg (23 Patients)
Tiredness	19 (83%)
Loose stools	6 (26%)
Fall	6 (26%)
Joint pain	6 (26%)
Back pain	6 (26%)

WERE THERE ANY SERIOUS MEDICAL PROBLEMS?

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

A total of 9 patients (39%, or 9 out of 23 patients) had serious medical problems. The doctors thought that some of these serious medical problems were severe and these are listed in the following table.

There was 1 patient who died during the study due to suicide. The doctor did not think this death was related to enzalutamide.

Serious Medical Problems Considered Severe

Serious Medical Problem	Enzalutamide 160 mg (23 Patients)
Heart valve not working properly	1 (4%)
Loose stools	1 (4%)
Bleeding from the stomach	1 (4%)
Feeling weak and/or with no energy	1 (4%)
Back pain	1 (4%)
Throat cancer	1 (4%)
Suicide	1 (4%)
Blood in the urine	1 (4%)
Unable to completely empty the bladder (urinary retention)	1 (4%)
Unable to pass urine (urinary tract obstruction)	1 (4%)
Blood clot in a vein (deep vein thrombosis)	1 (4%)
Low blood pressure	1 (4%)

WHERE CAN I LEARN MORE ABOUT THIS STUDY?

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

For more details on this study protocol, please visit:

www.clinicaltrials.gov

Use the study identifier **NCT02384382**

Clinical trials with enzalutamide are ongoing and further trials are planned. 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!