

## WHY ZYTIGA® ?

(abiraterone acetate)

### ZYTIGA® Was Studied In Two Clinical Trials

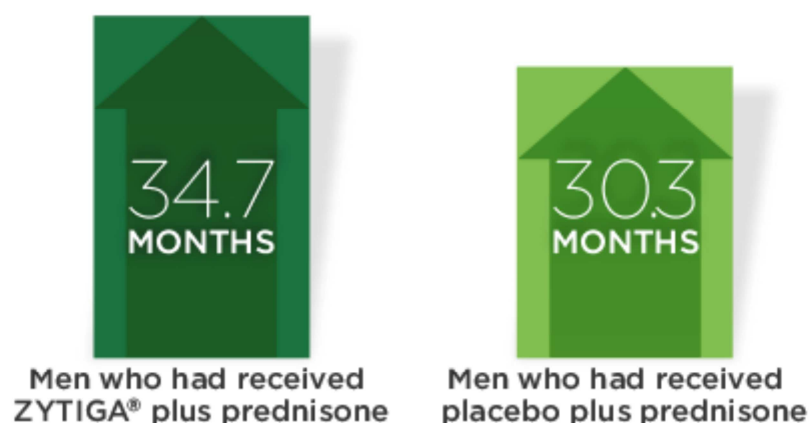
#### **In a Clinical Trial of Men with Metastatic Castration-Resistant Prostate Cancer (mCRPC) Who Had Not Received Prior Chemotherapy:**

In a clinical study of 1,088 men with mCRPC whose disease progressed while on therapy (ADT)<sup>1</sup> and who had not received prior chemotherapy:

**Certain men who received ZYTIGA® plus prednisone lived longer than men who received placebo (Placebo—An inactive substance or treatment that looks the same as, and is given the same way as, an active drug or treatment being tested. (National Cancer Institute: NCI Dictionary of Cancer Terms. Bethesda, MD: National Cancer Institute. 2013. Available at <http://www.cancer.gov/dictionary> <http://www.cancer.gov/dictionary> Accessed 5/13/2016.) plus prednisone.**

The was 34.7 months for the group of men who received ZYTIGA® plus prednisone, compared to 30.3 months for the group of men who received placebo plus prednisone. Please speak to your doctor about what this may mean to you.

#### MEDIAN OVERALL SURVIVAL



References:

<sup>1</sup>Androgen deprivation—A treatment to suppress or block the production or action of male hormones. (National Cancer Institute: NCI Dictionary of Cancer Terms. Bethesda, MD: National Cancer Institute. 2013. Available at [www.cancer.gov/dictionary](http://www.cancer.gov/dictionary). (<http://www.cancer.gov/dictionary>) Accessed 5/13/2016.)

<sup>2</sup>Placebo—An inactive substance or treatment that looks the same as, and is given the same way as, an active drug or treatment being tested. (National Cancer Institute: NCI Dictionary of Cancer Terms. Bethesda, MD: National Cancer Institute. 2013. Available at [www.cancer.gov/dictionary](http://www.cancer.gov/dictionary). (<http://www.cancer.gov/dictionary>) Accessed 5/13/2016.)

<sup>3</sup>Median overall survival—the length of time from either the date of diagnosis or the start of a clinical study or treatment for a disease, such as cancer, that half of the patients in a group of patients diagnosed with the disease are still alive. In a clinical trial, measuring the median overall survival is one way to see how well a new treatment works. Also called median survival. (National Cancer Institute: NCI Dictionary of Cancer Terms. Bethesda, MD: National Cancer Institute. 2013. Available at [www.cancer.gov/dictionary](http://www.cancer.gov/dictionary). (<http://www.cancer.gov/dictionary>) Accessed 5/13/2016.)

**In the same study, at a planned analysis, fewer men had progression as measured by imaging studies in the group who received ZYTIGA® plus prednisone compared to the group who received placebo plus prednisone.**

In the group of men who received ZYTIGA® plus prednisone, the median length of time they lived with the disease and it did not get worse was longer, as measured by imaging studies, compared to the group of men who received placebo plus prednisone.

65% (354 of 546) of men who received ZYTIGA® plus prednisone had progression, as measured by imaging studies.

71% (387 of 542) of men who received placebo plus prednisone had progression, as measured by imaging studies.

Please speak to your doctor about what this may mean to you.

The most common side effects of ZYTIGA® include:

Weakness

Joint swelling or pain

Swelling in your legs or feet

Hot flushes

Diarrhea

Vomiting

Cough

High blood pressure

Shortness of breath

Urinary tract infection

Bruising

Low red blood cells (anemia) and low blood potassium levels

High blood sugar levels, high blood cholesterol and triglycerides

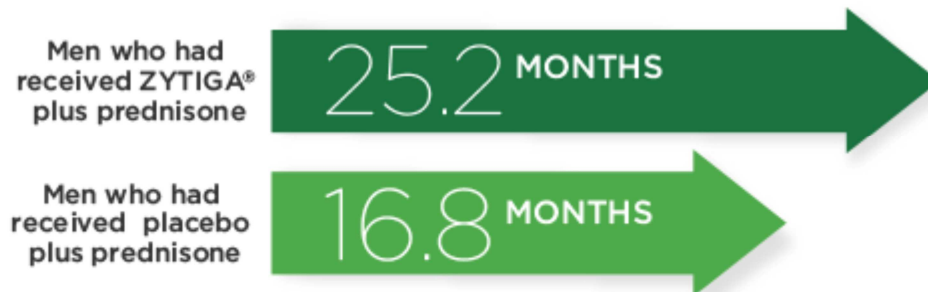
Certain other abnormal blood tests

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

**In the same study, ZYTIGA® plus prednisone delayed the start of chemotherapy compared to placebo plus prednisone in certain men.**

In the group of men who received ZYTIGA® plus prednisone, the median time to starting chemotherapy was 25.2 months compared to 16.8 months for the group of men who received placebo plus prednisone.

**MEDIAN TIME TO STARTING CHEMOTHERAPY**



**In a Trial of Men with Metastatic Castration-Resistant Prostate Cancer Who Received Prior Chemotherapy with Docetaxel:**

In another study of 1,195 men with mCRPC who had received chemotherapy with docetaxel:

**Certain men who received ZYTIGA® plus prednisone lived longer than those who received placebo plus prednisone.**

Certain men with mCRPC who had already received chemotherapy with docetaxel who received ZYTIGA® plus prednisone lived significantly longer than those who received placebo plus prednisone. In the updated analysis of the clinical trial, the median overall survival for men who received ZYTIGA® plus prednisone was 15.8 months, versus 11.2 months for men who received placebo plus prednisone. The primary analysis had shown that the median overall survival for men who received ZYTIGA® plus prednisone was 14.8 months, versus 10.9 months for men who received placebo plus prednisone.

**Talk with your doctor (/doctor-discussion-guide)** to see if ZYTIGA® is right for you.

**Who should not take ZYTIGA® (abiraterone acetate)?**

Do not take ZYTIGA® if you are pregnant or may become pregnant. ZYTIGA® may harm your unborn baby. Women who are pregnant or who may become pregnant should not touch ZYTIGA® without protection, such as gloves.

ZYTIGA® is not for use in women or children. **Keep ZYTIGA® and all medicines out of the reach of children.**

### **Before you take ZYTIGA®, tell your healthcare provider if you:**

Have heart problems

Have liver problems

Have a history of adrenal problems

Have a history of pituitary problems

Have any other medical conditions

Plan to become pregnant (**See "Who should not take ZYTIGA®?"**)

Are breastfeeding or plan to breastfeed. It is not known if ZYTIGA® passes into your breast milk. You and your healthcare provider should decide if you will take ZYTIGA® or breastfeed. You should not do both. (**See "Who should not take ZYTIGA®?"**)

Take any other medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements. ZYTIGA® can interact with many other medicines.

### **If you are taking ZYTIGA®:**

Take ZYTIGA® and prednisone exactly as your healthcare provider tells you.

Take your prescribed dose of ZYTIGA® one time a day. Your healthcare provider may change your dose if needed.

Do not stop taking your prescribed dose of ZYTIGA® or prednisone without talking to your healthcare provider first.

Take ZYTIGA® on an empty stomach. **Do not take ZYTIGA® with food.** Taking ZYTIGA® with food may cause more of the medicine to be absorbed by the body than is needed and this may cause side effects.

No food should be eaten 2 hours before and 1 hour after taking ZYTIGA®.

Swallow ZYTIGA® tablets whole. Do not crush or chew tablets.

Take ZYTIGA® tablets with water.

Your healthcare provider will do blood tests to check for side effects.

Men who are sexually active with a pregnant woman must use a condom during and for one week after treatment with ZYTIGA®. If their female partner may become pregnant a condom and another form of birth control must be used during and for one week after treatment with ZYTIGA®. Talk with your healthcare provider if you have any questions about birth control.

If you miss a dose of ZYTIGA® or prednisone, take your prescribed dose the following day. If you miss more than 1 dose, tell your healthcare provider right away.

### **ZYTIGA® may cause serious side effects including:**

**High blood pressure (hypertension), low blood potassium levels (hypokalemia), and fluid retention (edema).**

Tell your healthcare provider if you get any of the following symptoms:

Dizziness

Fast heartbeats

Feel faint or lightheaded

Headache

Confusion

Muscle weakness

Pain in your legs  
Swelling in your legs or feet

**Adrenal problems** may happen if you stop taking prednisone, get an infection, or are under stress.

**Liver problems.** You may develop changes in liver function blood tests. Your healthcare provider will do blood tests to check your liver before treatment with ZYTIGA® and during treatment with ZYTIGA®. Liver failure may occur, which can lead to death. Tell your healthcare provider if you notice any of the following changes:

Yellowing of the skin or eyes  
Darkening of the urine  
Severe nausea or vomiting

### **The most common side effects of ZYTIGA® include:**

Weakness  
Joint swelling or pain  
Swelling in your legs or feet  
Hot flushes  
Diarrhea  
Vomiting  
Cough  
High blood pressure  
Shortness of breath  
Urinary tract infection  
Bruising  
Low red blood cells (anemia) and low blood potassium levels  
High blood sugar levels, high blood cholesterol and triglycerides  
Certain other abnormal blood tests

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

**THESE ARE NOT ALL THE POSSIBLE SIDE EFFECTS OF ZYTIGA®.  
FOR MORE INFORMATION, ASK YOUR HEALTHCARE PROVIDER OR PHARMACIST.**

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

ZYTIGA® can interact with other medicines.

You should not start or stop any medicine before you talk with the healthcare provider that prescribed ZYTIGA®.

Know the medicines you take. Keep a list of them with you to show to your healthcare provider and pharmacist when you get a new medicine.

Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) (<http://www.fda.gov/medwatch>), or call 1-800-FDA-1088 (1-800-332-1088).

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**WHAT IS ZYTIGA®?**

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