

You are cordially invited to attend a live educational program

Please find registration details below.

Presented by

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Pgm Leader,
Genitourinary Medical Oncology
UCSF Helen Diller Family Comprehensive Cancer Center
Mill Valley, CA

Saturday, September 26, 2015

7:00 AM Continental Breakfast and Presentation
Please RSVP by September 16, 2015

Hyatt Regency - Sacramento

1209 L Street,
Sacramento, CA, 95814
916-443-1234

If you have any questions about this program, call **1-877-468-6720**.

The information you provide will only be used to facilitate your attendance at the program.

We look forward to your participation in this informative discussion.

Registration

To register, scan the code or log on to this site:

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Enter Code: 2015-11253



ZYTIGA® (abiraterone acetate): Key Clinical Findings for Patients With mCRPC That Has Progressed on Androgen Deprivation Therapy

Learning Objectives

- Discuss optimal strategies for early identification of metastases
- Examine the mechanism of action of ZYTIGA® (abiraterone acetate)
- Review evidence for the efficacy and safety of ZYTIGA® (abiraterone acetate) in metastatic castration-resistant prostate cancer (mCRPC)
- Discuss a case study of a patient with mCRPC

Indication

- ZYTIGA® (abiraterone acetate) in combination with prednisone is indicated for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC).

Important Safety Information

- The most common adverse reactions ($\geq 10\%$) are fatigue, joint swelling or discomfort, edema, hot flush, diarrhea, vomiting, cough, hypertension, dyspnea, urinary tract infection and contusion.
- The most common laboratory abnormalities ($>20\%$) are anemia, elevated alkaline

phosphatase, hypertriglyceridemia, lymphopenia, hypercholesterolemia, hyperglycemia, elevated AST, hypophosphatemia, elevated ALT and hypokalemia.

Contraindications

- ZYTIGA® (abiraterone acetate) is not indicated for use in women. ZYTIGA® can cause fetal harm (Pregnancy Category X) when administered to a pregnant woman and is contraindicated in women who are or may become pregnant.

Please see complete Important Safety Information on back and enclosed.
Please see accompanying full Prescribing Information.



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Important Safety Information

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Hypertension, Hypokalemia and Fluid Retention Due to Mineralocorticoid Excess - Use with caution in patients with a history of cardiovascular disease or with medical conditions that might be compromised by increases in blood pressure, hypokalemia, or fluid retention. ZYTIGA® may cause hypertension, hypokalemia, and fluid retention as a consequence of increased mineralocorticoid levels resulting from CYP17 inhibition. Safety has not been established in patients with LVEF <50% or New York Heart Association (NYHA) Class III or IV heart failure (in Study 1) or NYHA Class II to IV heart failure (in Study 2) because these patients were excluded from these randomized clinical trials. Control hypertension and correct hypokalemia before and during treatment. Monitor blood pressure, serum potassium, and symptoms of fluid retention at least monthly.

Adrenocortical Insufficiency (AI) - AI was reported in patients receiving ZYTIGA® in combination with prednisone, after an interruption of daily steroids and/or with concurrent infection or stress. Use caution and monitor for symptoms and signs of AI if prednisone is stopped or withdrawn, if prednisone dose is reduced, or if the patient experiences unusual stress. Symptoms and signs of AI may be masked by adverse

reactions associated with mineralocorticoid excess seen in patients treated with ZYTIGA®. Perform appropriate tests, if indicated, to confirm AI. Increased dosages of corticosteroids may be used before, during, and after stressful situations.

Hepatotoxicity - Monitor liver function and modify, withhold, or discontinue ZYTIGA® dosing as recommended (see Prescribing Information for more information). Measure serum transaminases [alanine aminotransferase (ALT) and aspartate aminotransferase (AST)] and bilirubin levels prior to starting treatment with ZYTIGA®, every two weeks for the first three months of treatment, and monthly thereafter. Promptly measure serum total bilirubin, AST, and ALT if clinical symptoms or signs suggestive of hepatotoxicity develop. Elevations of AST, ALT, or bilirubin from the patient's baseline should prompt more frequent monitoring. If at any time AST or ALT rise above five times the upper limit of normal (ULN) or the bilirubin rises above three times the ULN, interrupt ZYTIGA® treatment and closely monitor liver function.

Adverse Reactions - The most common adverse reactions (≥10%) are fatigue, joint swelling or discomfort, edema, hot flush, diarrhea, vomiting, cough, hypertension, dyspnea, urinary tract infection and contusion.

The most common laboratory abnormalities (>20%) are anemia, elevated alkaline phosphatase, hypertriglyceridemia, lymphopenia, hypercholesterolemia,

hyperglycemia, elevated AST, hypophosphatemia, elevated ALT and hypokalemia.

Drug Interactions - Based on *in vitro* data, ZYTIGA® is a substrate of CYP3A4. In a drug interaction trial, co-administration of rifampin, a strong CYP3A4 inducer, decreased exposure of abiraterone by 55%. Avoid concomitant strong CYP3A4 inducers during ZYTIGA® treatment. If a strong CYP3A4 inducer must be co-administered, increase the ZYTIGA® dosing frequency only during the co-administration period [see Dosage and Administration (2.3)]. In a dedicated drug interaction trial, co-administration of ketoconazole, a strong inhibitor of CYP3A4, had no clinically meaningful effect on the pharmacokinetics of abiraterone.

ZYTIGA® is an inhibitor of the hepatic drug-metabolizing enzymes CYP2D6 and CYP2C8. Avoid co-administration with CYP2D6 substrates with a narrow therapeutic index. If alternative treatments cannot be used, exercise caution and consider a dose reduction of the CYP2D6 substrate drug. In a CYP2C8 drug interaction trial in healthy subjects, the AUC of pioglitazone, a CYP2C8 substrate, was increased by 46% when administered with a single dose of ZYTIGA®. Patients should be monitored closely for signs of toxicity related to a CYP2C8 substrate with a narrow therapeutic index if used concomitantly with ZYTIGA®.

Use in Specific Populations - Do not use ZYTIGA® in patients with baseline severe hepatic impairment (Child-Pugh Class C).

034441-150514

www.zytigahcp.com

Please see accompanying full
Prescribing Information.

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**PLEASE NOTE: IT IS
REQUIRED THAT YOU
DELIVER THIS
INVITATION WITH A
COPY OF THE
CURRENT ZYTIGA[®]
(abiraterone acetate)
PRESCRIBING
INFORMATION.
THERE ARE TO BE NO
EXCEPTIONS TO THIS
REQUIREMENT.**