You are invited to attend

XOSPATA® (gilteritinib): A Targeted Therapeutic Approach for Relapsed or Refractory FLT3m+ AML Patients

PRESENTER

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DATE AND TIME

Friday, March 6, 2020
6:00 PM

LOCATION

Fleming's Prime Steakhouse & Wine Bar
905 North 54th Street
Chandler, AZ 85226

RSVP

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Kindly Reply by
02/28/2020

In the RSVP, please include your name, contact information, organization, and specialty.

Indication

XOSPATA is indicated for the treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with a FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test.

Select Safety Information

Contraindications

XOSPATA is contraindicated in patients with hypersensitivity to gilteritinib or any of the excipients. Anaphylactic reactions have been observed in clinical trials.

WARNING: DIFFERENTIATION SYNDROME

Patients treated with XOSPATA have experienced symptoms of differentiation syndrome, which can be fatal or life-threatening if not treated. Symptoms may include fever, dyspnea, hypoxia, pulmonary infiltrates, pleural or pericardial effusions, rapid weight gain or peripheral edema, hypotension, or renal dysfunction. If differentiation syndrome is suspected, initiate corticosteroid therapy and hemodynamic monitoring until symptom resolution.

Warnings and Precautions

Differentiation Syndrome (See BOXED WARNING) 3% of 319 patients treated with XOSPATA in the clinical trials experienced differentiation syndrome. Differentiation syndrome is associated with rapid proliferation and differentiation of myeloid cells and may be life-threatening or fatal if not treated. Symptoms of differentiation syndrome in patients treated with XOSPATA included fever, dyspnea, pleural effusion, pericardial effusion, pulmonary edema, hypotension, rapid weight gain, peripheral edema, rash, and renal dysfunction. Some cases had concomitant acute febrile neutrophilic dermatosis. Differentiation syndrome occurred as early as 2 days and up to 75 days after XOSPATA initiation and has been observed with or without concomitant leukocytosis. If differentiation syndrome is suspected, initiate dexamethasone 10 mg IV every 12 hours (or an equivalent dose of an alternative oral or IV corticosteroid) and hemodynamic monitoring until improvement. Taper corticosteroids after resolution of symptoms and administer corticosteroids for a minimum of 3 days. Symptoms of differentiation syndrome may recur with premature discontinuation of corticosteroid treatment. If severe signs and/or symptoms persist for more than 48 hours after initiation of corticosteroids, interrupt XOSPATA until signs and symptoms are no longer severe.

Please see additional Important Safety Information on the next page.
Please click here for full Prescribing Information.

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gilteritinib 40mg tablets

Important Safety Information

Warnings and Precautions

Posterior Reversible Encephalopathy Syndrome (PRES) 1% of 319 patients treated with XOSPATA in the clinical trials experienced posterior reversible encephalopathy syndrome (PRES) with symptoms including seizure and altered mental status. Symptoms have resolved after discontinuation of XOSPATA. A diagnosis of PRES requires confirmation by brain imaging, preferably magnetic resonance imaging (MRI). Discontinue XOSPATA in patients who develop PRES.

Prolonged QT Interval XOSPATA has been associated with prolonged cardiac ventricular repolarization (QT interval). 1% of the 317 patients with a post-baseline QTc measurement on treatment with XOSPATA in the clinical trial were found to have a QTc interval greater than 500 msec and 7% of patients had an increase from baseline QTc greater than 60 msec. Perform electrocardiogram (ECG) prior to initiation of treatment with XOSPATA, on days 8 and 15 of cycle 1, and prior to the start of the next two subsequent cycles. Interrupt and reduce XOSPATA dosage in patients who have a QTcF >500 msec. Hypokalemia or hypomagnesemia may increase the QT prolongation risk. Correct hypokalemia or hypomagnesemia prior to and during XOSPATA administration.

Pancreatitis 4% of 319 patients treated with XOSPATA in the clinical trials experienced pancreatitis. Evaluate patients who develop signs and symptoms of pancreatitis. Interrupt and reduce the dose of XOSPATA in patients who develop pancreatitis.

Embryo-Fetal Toxicity XOSPATA can cause embryo-fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with XOSPATA and for at least 6 months after the last dose of XOSPATA. Advise males with female partners of reproductive potential to use effective contraception during treatment with XOSPATA and for at least 4 months after the last dose of XOSPATA. Pregnant women, patients becoming pregnant while receiving XOSPATA or male patients with pregnant female partners should be apprised of the potential risk to the fetus.

Adverse Reactions

Fatal adverse reactions occurred in 2% of patients receiving XOSPATA. These were cardiac arrest (1%) and one case each of differentiation syndrome and pancreatitis. The most frequent (≥5%) nonhematological serious adverse reactions reported in patients were fever (13%), dyspnea (9%), renal impairment (8%), transaminase increased (6%) and noninfectious diarrhea (5%).

7% discontinued XOSPATA treatment permanently due to an adverse reaction. The most common (>1%) adverse reactions leading to discontinuation were aspartate aminotransferase increased (2%) and alanine aminotransferase increased (2%).

The most frequent (≥5%) grade ≥3 nonhematological adverse reactions reported in patients were transaminase increased (21%), dyspnea (12%), hypotension (7%), mucositis (7%), myalgia/arthralgia (7%), and fatigue/malaise (6%).

Other clinically significant adverse reactions occurring in ≤10% of patients included: electrocardiogram QT prolonged (9%), hypersensitivity (8%), pancreatitis (5%), cardiac failure (4%), pericardial effusion (4%), acute febrile neutrophilic dermatosis (3%), differentiation syndrome (3%), pericarditis/myocarditis (2%), large intestine perforation (1%), and posterior reversible encephalopathy syndrome (1%).

Lab Abnormalities Shifts to grades 3-4 nonhematologic laboratory abnormalities in XOSPATA treated patients included phosphate decreased (14%), alanine aminotransferase increased (13%), sodium decreased (12%), aspartate aminotransferase increased (10%), calcium decreased (6%), creatine kinase increased (6%), triglycerides increased (6%), creatinine increased (3%), and alkaline phosphatase increased (2%).

Drug Interactions

Combined P-gp and Strong CYP3A Inducers Concomitant use of XOSPATA with a combined P-gp and strong CYP3A inducer decreases XOSPATA exposure which may decrease XOSPATA efficacy. Avoid concomitant use of XOSPATA with combined P-gp and strong CYP3A inducers.

Strong CYP3A inhibitors Concomitant use of XOSPATA with a strong CYP3A inhibitor increases XOSPATA exposure. Consider alternative therapies that are not strong CYP3A inhibitors. If the concomitant use of these inhibitors is considered essential for the care of the patient, monitor patient more frequently for XOSPATA adverse reactions. Interrupt and reduce XOSPATA dosage in patients with serious or life-threatening toxicity.

Drugs that Target 5HT2B Receptor or Sigma Nonspecific Receptor Concomitant use of XOSPATA may reduce the effects of drugs that target the 5HT2B receptor or the sigma nonspecific receptor (e.g., escitalopram, fluoxetine, sertraline). Avoid concomitant use of these drugs with XOSPATA unless their use is considered essential for the care of the patient.

Specific Populations

Lactation Advise women not to breastfeed during treatment with XOSPATA and for 2 months after the last dose.

Important Notice

Astellas Pharma US, Inc. ("Astellas") is subject to U.S. Federal and State transparency laws that require Astellas to track and report meals and other transfers of value provided to certain U.S. health care professionals (including physicians). To comply with these obligations, for attendees who receive any portion of the meal provided at this program, Astellas will report the attendee's name and the value of the meal received. Astellas offers you the option to attend the event but not receive the meal. Please ask the Program Organizer for more information about this opt-out option.

Additional restrictions apply to the following individuals:

For U.S. Healthcare Providers in Vermont or those affiliated with the U.S. Department of Veterans Affairs or Department of Defense: Several states and federal agencies in the United States restrict your interactions with Astellas, including the provision of in-kind benefits (such as meals) at company-sponsored events. If you are a healthcare professional in Vermont or are affiliated with the U.S. Department of Veterans Affairs, Department of Defense, or other federal executive branch entity, or any state government entity that prohibits your acceptance of this meal, Astellas policy prohibits providing you a meal at this program. If you would like to attend, but not partake in the meal, please refer to the opt-out option below.

For U.S. Licensed Prescribers in Minnesota: Under Minnesota law, Astellas may provide meals and other transfers of value to Minnesota licensed prescribers if the annual (calendar year) aggregate total of all value transfers of any kind from Astellas to a Minnesota prescriber does not exceed $50.00 USD, subject to some exceptions. Astellas has policies and procedures that are intended to help ensure compliance with this annual aggregate limit. If you have questions about your annual aggregate value transfers from Astellas or the impact of accepting the meal provided at this event on your annual total, please consult the Program Organizer. In addition, if you would like to attend, but not partake in the meal, please refer to the opt-out option below.

For Foreign Healthcare Providers: Some foreign countries restrict the provision of or require the reporting of in-kind benefits (such as meals) to health care professionals at company-sponsored events. Astellas has policies and procedures that are intended to help ensure compliance with these requirements and restrictions. To help ensure compliance with applicable requirements, Astellas policy prohibits providing a meal to you in conjunction with this event. If you would like to attend, but not partake in the meal, please refer to the opt-out option below.

Opt-Out Option: Astellas offers an opt-out option that allows you to still attend this event but not receive the meal. Please ask the Program Organizer for more information about the opt-out option.

Astellas has adopted the PhRMA Code on Interactions with Healthcare Professionals, which is designed to foster ethical relationships with healthcare professionals. In accordance with the PhRMA Code, we will not pay for the expenses of a healthcare professional's spouse or guest, and such individuals should not attend the program, unless they have a bona fide professional interest in the information being shared at the program. We appreciate your understanding and support of our commitment to these ethical standards.

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