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

PRESENTER

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LOCATION

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DATE AND TIME

Tuesday, May 21, 2019
6:30 PM

RSVP

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Kindly Reply by
05/14/2019
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.

WARNINGS AND PRECAUTIONS

Posterior Reversible Encephalopathy Syndrome (PRES) There have been rare reports of PRES with symptoms including seizure and altered mental status with XOSPATA. Symptoms have resolved after discontinuation of XOSPATA. A diagnosis of PRES requires confirmation by brain imaging, preferably MRI. Discontinue XOSPATA in patients who develop PRES.

Prolonged QT Interval XOSPATA has been associated with prolonged cardiac ventricular repolarization (QT interval). Of the 292 patients treated with XOSPATA in the clinical trial, 1.4% 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 There have been rare reports of pancreatitis in patients receiving XOSPATA in clinical studies. Evaluate patients who develop signs and symptoms of pancreatitis. Interrupt and reduce the dose of XOSPATA in patients who develop pancreatitis.

Embryo-Fetal Toxicity Based on findings in animals and its mechanism of action, 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.

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ON THE NEXT PAGE.
PLEASE CLICK HERE FOR ACCOMPANYING FULL PRESCRIBING INFORMATION.

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IMPORTANT SAFETY INFORMATION (CONT.)

ADVERSE REACTIONS

The most frequent non-hematological serious adverse reactions (≥5%) reported in patients were pneumonia (19%), sepsis (13%), fever (13%), dyspnea (7%) and renal impairment (5%).

Overall, 22 of 292 patients (8%) discontinued XOSPATA treatment permanently due to an adverse reaction. The most common adverse reactions (>1%) leading to discontinuation were pneumonia (2%), sepsis (2%) and dyspnea (1%). The most common adverse reactions (≥20%) were myalgia/arthralgia (42%), transaminase increased (41%), fatigue/malaise (40%), fever (35%), non-infectious diarrhea (34%), dyspnea (34%), edema (34%), rash (30%), pneumonia (30%), nausea (27%), stomatitis (26%), cough (25%), headache (21%), hypotension (21%), dizziness (20%) and vomiting (20%).

Other clinically significant adverse reactions occurring in ≤10% of patients included: electrocardiogram QT prolonged (7%), cardiac failure (grouped terms) (4%), pericardial effusion (3%), pericarditis (2%), differentiation syndrome (1%), anaphylactic reaction (1%) and posterior reversible encephalopathy syndrome (1%).

Lab Abnormalities: The most common lab abnormalities (>20%) that were Grade ≥3 that occurred ≥10% were: hypophosphatemia (12%), alanine aminotransferase increased (12%), hyponatremia (12%), aspartate aminotransferase increased (10%).

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, 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.

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