Recognizing Resistance to and Intolerance of Hydroxyurea in Polycythemia Vera Patients: A Case-Based Approach

Wednesday, February 8, 2017 6:30 PM - 8:30 PM

Featured Speaker:

Jason Salganick, MD Ironwood Cancer and Research Centers Phoenix, AZ

Location:

Le Papillon 410 Saratoga Avenue San Jose, CA, 95129

Program Objectives:

- Provide an overview of PV
- Review clinical considerations for patients with PV
- Discuss how to identify patients with uncontrolled PV despite treatment with HU
- Discuss characteristics of actual patients from the RESPONSE trial
- Provide an overview of efficacy, safety, and dosing information for Jakafi

REGISTRATION FORM

Please print clearly.

First and Last Name:			
Title or Degree			
State(s) and State License #(s):			
Affiliation:			
Affiliation Address (Street)			
City	State	ZIP	
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Phone			

Register by February 1, 2017 INC-3624

To register for the program, please return the following information to: Steven Knauf at S Phase by e-mail to sknauf@sphase.com, fax to (404)865-1290, or call (770)980-3145.

Questions regarding this program can be directed to your Incyte Territory Business Manager, Andy Wong, at (415)606-5106 or awong@incyte.com.

Prior to registering, please review the program title and speaker to ensure you have not attended this program within the past year.

INDICATIONS AND USAGE

Jakafi® (ruxolitinib) is indicated for treatment of patients with polycythemia vera who have had an inadequate response to or are intolerant of hydroxyurea.

Jakafi is indicated for treatment of patients with intermediate or high-risk myelofibrosis (MF), including primary MF, post–polycythemia vera MF and post–essential thrombocythemia MF.

Please see Important Safety Information on back cover and attached Full Prescribing Information.

This program is sponsored by Incyte Corporation and not eligible for CE credits. Please note this program is intended for healthcare professionals (HCPs) only.

Consistent with PhRMA Guidelines, spouses and other guests of the HCP are not permitted to attend. The cost of meals associated with this event may be disclosed consistent with applicable federal and state law disclosure requirements. State and federal laws and regulations may restrict state or federal employees from receiving meals. By attending this event, you confirm that you have obtained any necessary approvals from your employer. HCPs may be subject to state law restrictions regarding attendance. HCPs licensed in Vermont, or employees/agents of Vermont HCPs may not attend this event. Minnesota law restricts Incyte from offering meals or other refreshments at speaker events to certain healthcare professionals who are licensed in Minnesota and have the ability to prescribe prescription drugs (eg, physicians, physician assistants, nurse practitioners, advanced nurses). If you are licensed to prescribe in Minnesota, please identify yourself on this document and inform an Incyte representative prior to the start of the program.

IMPORTANT SAFETY INFORMATION

- Treatment with Jakafi® (ruxolitinib) can cause thrombocytopenia, anemia and neutropenia, which are each dose-related
 effects. Perform a pre-treatment complete blood count (CBC) and monitor CBCs every 2 to 4 weeks until doses are
 stabilized, and then as clinically indicated
- Manage thrombocytopenia by reducing the dose or temporarily interrupting Jakafi. Platelet transfusions may be necessary
- Patients developing anemia may require blood transfusions and/or dose modifications of Jakafi
- Severe neutropenia (ANC $< 0.5 \times 10^9$ /L) was generally reversible by withholding Jakafi until recovery
- Serious bacterial, mycobacterial, fungal and viral infections have occurred. Delay starting Jakafi until active serious infections have resolved. Observe patients receiving Jakafi for signs and symptoms of infection and manage promptly
- Tuberculosis (TB) infection has been reported. Observe patients taking Jakafi for signs and symptoms of active TB and
 manage promptly. Prior to initiating Jakafi, evaluate patients for TB risk factors and test those at higher risk for latent
 infection. Consult a physician with expertise in the treatment of TB before starting Jakafi in patients with evidence of active
 or latent TB. Continuation of Jakafi during treatment of active TB should be based on the overall risk-benefit determination
- Progressive multifocal leukoencephalopathy (PML) has occurred with ruxolitinib treatment for myelofibrosis. If PML is suspected, stop Jakafi and evaluate
- Advise patients about early signs and symptoms of herpes zoster and to seek early treatment
- Increases in hepatitis B viral load with or without associated elevations in alanine aminotransferase and aspartate aminotransferase have been reported in patients with chronic hepatitis B virus (HBV) infections. Monitor and treat patients with chronic HBV infection according to clinical guidelines
- When discontinuing Jakafi, myeloproliferative neoplasm-related symptoms may return within one week. After
 discontinuation, some patients with myelofibrosis have experienced fever, respiratory distress, hypotension, DIC, or
 multi-organ failure. If any of these occur after discontinuation or while tapering Jakafi, evaluate and treat any intercurrent
 illness and consider restarting or increasing the dose of Jakafi. Instruct patients not to interrupt or discontinue Jakafi
 without consulting their physician. When discontinuing or interrupting Jakafi for reasons other than thrombocytopenia or
 neutropenia, consider gradual tapering rather than abrupt discontinuation
- Non-melanoma skin cancers including basal cell, squamous cell, and Merkel cell carcinoma have occurred. Perform
 periodic skin examinations
- Treatment with Jakafi has been associated with increases in total cholesterol, low-density lipoprotein cholesterol, and triglycerides. Assess lipid parameters 8-12 weeks after initiating Jakafi. Monitor and treat according to clinical guidelines for the management of hyperlipidemia
- The three most frequent non-hematologic adverse reactions (incidence >10%) were bruising, dizziness and headache
- A dose modification is recommended when administering Jakafi with strong CYP3A4 inhibitors or fluconazole or in
 patients with renal or hepatic impairment. Patients should be closely monitored and the dose titrated based on safety and
 efficacy
- Use of Jakafi during pregnancy is not recommended and should only be used if the potential benefit justifies the potential risk to the fetus. Women taking Jakafi should not breast-feed

