



Jakafi® (ruxolitinib) Prescribing Information Updated with Expanded Dosing Guidance and New Safety Information

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WILMINGTON, Del.--(BUSINESS WIRE)--Jun. 12, 2013-- Incyte Corporation (Nasdaq: INCY) announced today that the U.S. Food and Drug Administration (FDA) has updated prescribing information for Jakafi® (ruxolitinib) to include new recommended dosing guidance for patients with low platelet counts and additional safety information. Approved in November 2011, Jakafi is the first and only FDA-approved product for the treatment of patients with intermediate or high-risk myelofibrosis.

The prescribing information for Jakafi now includes a new recommended starting dose of 5 mg twice daily of Jakafi for patients with baseline platelet counts between 50–100 x 10⁹/L (50,000 to 100,000) and the flexibility for subsequent dose modifications based on safety and efficacy. The FDA decision to expand the dosing information followed a review of the supplemental New Drug Application (sNDA), which included data from an ongoing Phase II trial (Study 258) of patients with baseline platelet counts of 50,000 to 100,000. In this trial, the starting dose of 5 mg twice daily could be adjusted up or down based on protocol defined hematology criteria with a target dose of 10 mg twice daily to achieve clinical response. The safety and efficacy findings from the current interim analysis of Study 258 are generally consistent with the results observed in the pivotal, phase III COMFORT-I and COMFORT-II program.

"The expanded dosing guidance provides physicians with important new information intended to help patients with low platelet counts experience the clinical benefits of Jakafi, including meaningful spleen reduction and symptom improvement," stated Paul Friedman, M.D., Incyte's President and Chief Executive Officer.

Additionally, new safety information has been added to the Warnings and Precautions section of the prescribing information stating: Progressive multifocal leukoencephalopathy (PML) has been reported with ruxolitinib treatment for myelofibrosis. If PML is suspected, stop Jakafi and evaluate.

Language has also been added to the Patient Counseling Information section advising healthcare professionals to inform patients regarding the early signs and symptoms of PML.

These changes to the prescribing information are based on one known case of PML with an undetermined relationship to ruxolitinib in the approximately 9,800 myelofibrosis patients treated with ruxolitinib worldwide in clinical trials or with commercial product. There are reports in the medical literature to suggest that patients with myeloproliferative neoplasms, including myelofibrosis, may be at higher risk of developing PML¹⁻⁴.

The newly revised Prescribing Information is available at www.incyte.com.

About Jakafi

Jakafi is a prescription medicine used to treat people with intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF. Jakafi is marketed by Incyte in the United States and by Novartis as Jakavi® (ruxolitinib) outside the United States.

Important Safety Information

Jakafi can cause serious side effects including:

Low blood counts: Jakafi may cause your platelet, red blood cell, or white blood cell counts to be lowered. If you develop bleeding, stop taking Jakafi and call your healthcare provider. Your healthcare provider will perform blood tests to check your blood counts before you start Jakafi and regularly during your treatment. Your healthcare provider may change your dose of Jakafi or stop your treatment based on the results of your blood tests. Tell your healthcare provider right away if you experience unusual bleeding, bruising, fatigue, shortness of breath, or a fever.

Infection: You may be at risk for developing a serious infection while taking Jakafi. Tell your healthcare provider if you develop symptoms such as chills, nausea, vomiting, aches, weakness, fever, or painful skin rash or blisters.

The most common side effects of Jakafi include dizziness and headache.

These are not all the possible side effects of Jakafi. Ask your healthcare provider or pharmacist for more information. Tell your healthcare provider about any side effect that bothers you or that does not go away.

Before taking Jakafi, tell your healthcare provider about all the medications, vitamins, and herbal supplements you are taking and all your medical conditions, including if you have an infection, have or had liver or kidney problems, are on dialysis, or have any other medical condition. Do not drink grapefruit juice while taking Jakafi.

Women should not take Jakafi while pregnant or planning to become pregnant, or if breast-feeding.

Please see the Full Prescribing Information available at www.incyte.com, which includes a more complete discussion of the risks associated with Jakafi.

About Myelofibrosis

Myelofibrosis (MF) is a life-threatening blood cancer that belongs to a group of diseases referred to as myeloproliferative neoplasms (or MPNs). MF has a poor prognosis and limited treatment options.^{5,6} While the exact prevalence of MF is uncertain, and estimates vary widely, based on extensive

market research, Incyte estimates MF affects about 16,000 to 18,500 people in the U.S.⁷ The enlarged spleen and debilitating symptoms of MF are linked to dysregulated signaling in the Janus kinase (JAK) pathway. This dysregulation may be caused by various mechanisms and mutations, such as the JAK2 V617F mutation.^{8,9} Although allogeneic stem cell transplantation may cure myelofibrosis, the procedure is associated with significant morbidity and transplant-related mortality and is available to less than 5 percent of patients who are young and fit enough to undergo the procedure.¹⁰

About Incyte

Incyte Corporation is a Wilmington, Delaware-based biopharmaceutical company focused on the discovery, development and commercialization of proprietary small molecule drugs for oncology and inflammation. For additional information on Incyte, please visit the Company's website at www.incyte.com.

Forward Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including the statement with respect to the expanded dosing guidance providing physicians with important new information intended to help patients with low platelet counts experience the clinical benefits of Jakafi, including meaningful spleen reduction and symptom improvement, contain predictions, estimates and other forward-looking statements. These forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to the efficacy or safety of Jakafi, the acceptance of Jakafi in the marketplace, risks related to market competition, the results of further research and development, and other risks detailed from time to time in Incyte's filings with the Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the quarter ended March 31, 2013. Incyte disclaims any intent or obligation to update these forward-looking statements.

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