NCCN Guidelines® Recommend Jakafi® (ruxolitinib) for the Treatment of Myelofibrosis

September 27, 2016

Treatment guidelines for myeloproliferative neoplasms (MPNs) focused on the treatment of myelofibrosis (MF), a rare blood cancer, published today

WILMINGTON, Del.--(BUSINESS WIRE)--Sep. 27, 2016-- Incyte Corporation (Nasdaq: INCY) today announced that its first-in-class JAK1/JAK2 inhibitor, Jakafi® (ruxolitinib), has been included as a recommended treatment in the latest National Comprehensive Cancer Network® (NCCN®) Clinical Practice Guidelines in Oncology for myelofibrosis (MF).

“Jakafi is the first FDA-approved treatment for patients with intermediate or high-risk MF, representing an important advancement for patients,” said Peg Squier, M.D., Ph.D., Incyte’s Head of U.S. Medical Affairs. “We are pleased that Jakafi has been recommended in the first set of NCCN treatment guidelines for MPNs, which will help inform healthcare providers’ treatment decisions for patients with MF. We believe that this underscores the important and long-term clinical benefits seen in patients treated with Jakafi.”

MF is part of a group of related rare blood cancers known as myeloproliferative neoplasms (MPNs). In MF, a patient’s bone marrow can no longer produce enough normal blood cells, causing the spleen and or liver to become enlarged.[1] MF is a progressive disease, which leads to bone marrow scarring and significant debilitating disease-related symptoms such as anemia, fatigue, and itching which can result in a poor quality of life.[2] Patients with MF have a decreased life expectancy, with an average survival of approximately five to six years.[3] The cause of MF is unknown but is linked to genetic mutations—between 50% and 60% of people with MF have a specific mutation of the Janus Kinase 2 gene (JAK2).[4]

The new NCCN Guidelines are available online at www.nccn.org.

About Jakafi (ruxolitinib)

Jakafi is a first-in-class JAK1/JAK2 inhibitor approved by the U.S. Food and Drug Administration, for treatment of people with intermediate or high-risk myelofibrosis (MF), including primary MF, post–polycythemia vera MF, and post–essential thrombocythemia MF.

Jakafi is also indicated for treatment of people with polycythemia vera (PV) who have had an inadequate response to or are intolerant of hydroxyurea.

Jakafi is marketed by Incyte in the United States and by Novartis as Jakavi® (ruxolitinib) outside the United States. Jakafi is a registered trademark of Incyte Corporation. Jakavi is a registered trademark of Novartis AG in countries outside the United States.

Important Safety Information

Jakafi can cause serious side effects, including:

Low blood counts: Jakafi® (ruxolitinib) 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 develop or have worsening symptoms such as unusual bleeding, bruising, tiredness, shortness of breath, or a fever.

Infection: You may be at risk for developing a serious infection during treatment with Jakafi. Tell your healthcare provider if you develop any of the following symptoms of infection: chills, nausea, vomiting, aches, weakness, fever, painful skin rash or blisters.

Skin cancers: Some people who take Jakafi have developed certain types of non-melanoma skin cancers. Tell your healthcare provider if you develop any new or changing skin lesions.

Increases in Cholesterol: You may have changes in your blood cholesterol levels. Your healthcare provider will do blood tests to check your cholesterol levels during your treatment with Jakafi.

The most common side effects of Jakafi include: low platelet count, low red blood cell counts, bruising, dizziness, headache.

These are not all the possible side effects of Jakafi. Ask your pharmacist or healthcare provider 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 tuberculosis (TB), or have been in close contact with someone who has TB, have or had hepatitis B, have or had liver or kidney problems, are on dialysis, had skin cancer or have any other medical condition. Take Jakafi exactly as your healthcare provider tells you. Do not change or stop taking Jakafi without first talking to your healthcare provider. Do not drink grapefruit juice while on Jakafi.

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

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

About National Comprehensive Cancer Network

The National Comprehensive Cancer Network® (NCCN®), a not-for-profit alliance of 27 of the world's leading cancer centers devoted to patient care, research, and education, is dedicated to improving the quality, effectiveness, and efficiency of cancer care so that patients can live better lives. Through the leadership and expertise of clinical professionals at NCCN Member Institutions, NCCN develops resources that present valuable information to the numerous stakeholders in the health care delivery system. As the arbiter of high-quality cancer care, NCCN promotes the importance of continuous quality improvement and recognizes the significance of creating clinical practice guidelines appropriate for use by patients, clinicians, and other health care decision-makers.

About Incyte

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

Follow @Incyte on Twitter at https://twitter.com/Incyte.

1 Leukemia & Lymphoma Society. "Myelofibrosis Facts." Available at: http://www.lls.org/sites/default/files/file_assets/FS14_Myelofibrosis_Fact%20Sheet_Final9.12.pdf. Accessed November 2015.

2 Mesa RA, Schwagera S, Radia D, et al. The Myelofibrosis Symptom Assessment Form (MFSAF): An Evidence-based Brief Inventory to Measure Quality of Life and Symptomatic Response to Treatment in Myelofibrosis. *Leuk Res*. 2009;33:1199-1203.

3 Gangat N, Caramazza D, Vaidya R, et al. DIPSS-plus: A Refined Dynamic International Prognostic Scoring System (DIPSS) for Primary Myelofibrosis that Incorporates Prognostic Information from Karyotype, Platelet Count and Transfusion Status. *J Clin Oncol.* 2011; 29:392-397.

4 Patriarca F1, Bacigalupo A, Sperotto A, et al. Allogeneic hematopoietic stem cell transplantation in myelofibrosis: the 20-year experience of the Gruppo Italiano Trapianto di Midollo Osseo (GITMO). Haematologica. 2008; 93:1514-1522.

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Source: Incyte Corporation

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