FDA Accepts Supplemental New Drug Application for Jakafi® (ruxolitinib) and Priority Review Granted

August 5, 2014

WILMINGTON, Del.--(BUSINESS WIRE)--Aug. 5, 2014-- Incyte Corporation (Nasdaq:INCY) today announced that the U.S. Food and Drug Administration (FDA) has accepted for filing the supplemental New Drug Application (sNDA) for ruxolitinib as a potential treatment of patients with polycythemia vera (PV) who have had an inadequate response to or are intolerant of hydroxyurea. The sNDA includes results from the RESPONSE Phase III trial, which were recently presented at the 2014 American Society of Clinical Oncology (ASCO) annual meeting. RESPONSE was conducted under a Special Protocol Assessment (SPA) from the FDA.

The Prescription Drug User Fee Act (PDUFA) date for the sNDA for ruxolitinib is set for December 5, 2014.

“We are pleased to have received the acceptance of our sNDA filing by the FDA, and we believe that the submission contains a robust data set,” stated Richard Levy, M.D., Executive Vice President and Chief Drug Development and Medical Officer of Incyte. “We look forward to working with the FDA to complete its review of this application”.

PV is a form of blood cancer leading to the overproduction of normal red blood cells, white blood cells and platelets. Patients with uncontrolled PV have an increased risk of cardiovascular complications such as stroke, pulmonary embolism, deep vein thrombosis and heart attack.

Jakafi is the first and only FDA-approved treatment for patients with intermediate or high-risk myelofibrosis (MF), including primary MF, post–polycythemia vera MF and post–essential thrombocythemia MF. Ruxolitinib is also the first JAK1/JAK2 inhibitor to demonstrate efficacy in a Phase III trial in patients with polycythemia vera and, if approved, would be the first JAK1/JAK2 inhibitor made available to patients with polycythemia vera in the U.S.

About Polycythemia Vera

Polycythemia vera (PV) is a myeloproliferative neoplasm (MPN) characterized by an overproduction of normal red blood cells, white blood cells and platelets that leads to an increased risk of thrombosis.[1-4] Erythrocytosis (elevated red blood cell mass) is the most prominent clinical manifestation of PV, distinguishing it from other MPNs.[5] PV may occur at any age but often presents later in life, with a median age at diagnosis of 60 years.[6,7] Approximately 100,000 patients in the United States are living with PV[8] and approximately 25 percent of patients with PV develop resistance to or intolerance of hydroxyurea[9,10] and are considered uncontrolled.

About Jakafi® (ruxolitinib)

Jakafi is a prescription medicine approved by the U.S. Food and Drug Administration 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. 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.

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

About Incyte

Incyte Corporation is a Wilmington, Delaware-based biopharmaceutical company focused on the discovery, development and commercialization of proprietary small molecule drugs, primarily for oncology. 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 without limitation statements with respect to the potential efficacy, safety and therapeutic value of ruxolitinib in polycythemia vera, including the potential for ruxolitinib to become the first JAK1/JAK2 inhibitor available for patients with polycythemia vera in the U.S., and working with the FDA to complete its review of the supplemental New Drug Application, contain predictions and estimates and are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on Incyte's current expectations and 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 ruxolitinib, the results of further research and development, the high degree of risk and uncertainty associated with drug development, clinical trials and regulatory approval processes, other market or economic factors, competitive and technological advances, 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 June 30, 2014. Incyte disclaims any intent or obligation to update these forward-looking statements.

References

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Source: Incyte Corporation

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