Incyte Announces U.S. FDA Has Extended the Review Period for Ruxolitinib (Jakafi®) in Acute Graft-Versus-Host Disease

February 7, 2019

WILMINGTON, Del.--(BUSINESS WIRE)--Feb. 7, 2019-- Incyte (Nasdaq:INCY)announced today that the U.S. Food and Drug Administration (FDA) has extended the review period for the supplemental New Drug Application (sNDA) for ruxolitinib (Jakafi®) for the treatment of patients with acute graft-versus-host disease (GVHD) who have had an inadequate response to corticosteroids. The new Prescription Drug User Fee Act (PDUFA) target action date is May 24, 2019.

The FDA extended the action date to allow time to review additional data submitted by Incyte in response to the FDA's information requests. The submission of the additional information has been determined by the FDA to constitute a Major Amendment to the sNDA, resulting in an extension of the PDUFA goal date by three months.

"We remain confident in the data supporting our sNDA submission and look forward to continued dialogue with the FDA throughout the review process," said Steven Stein, M.D., Chief Medical Officer, Incyte. "We are committed to bringing ruxolitinib forward as a treatment option for patients with acute GVHD."

The sNDA for ruxolitinib for the treatment of patients with acute GVHD was submitted in August 2018, and the FDA granted both Priority Review and Breakthrough Therapy Designation. The FDA grants Priority Review to medicines that have the potential to provide significant improvements in the treatment of a serious disease. The FDA's Breakthrough Therapy Designation is designed to expedite the development and review of drugs for serious conditions that have shown encouraging early clinical results and may demonstrate substantial improvements over available medicines. Additionally, the FDA granted ruxolitinib Orphan Drug Designation for the treatment of GVHD, a designation granted to investigational compounds intended for the safe and effective treatment, diagnosis or prevention of rare diseases or disorders that affect fewer than 200,000 people.

About GVHD

GVHD is a condition that can occur after an allogeneic stem cell transplant (the transfer of stem cells from a donor), where the donated cells initiate an immune response and attack the transplant recipients organs, leading to significant morbidity and mortality. There are two forms of GVHD, acute and chronic, which can affect multiple organ systems including the skin, gastrointestinal (digestive) tract and liver.

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 polycythemia vera (PV) who have had an inadequate response to or are intolerant of hydroxyurea.

Jakafi is also indicated 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 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. Ruxolitinib is also being evaluated in patients with acute and chronic GVHD who have an inadequate response to corticosteroids in the REACH2 and REACH3 clinical studies, respectively. It is expected that these two pivotal studies will complete in 2019, and could support additional regulatory submissions, in the U.S. by Incyte and ex-U.S. by Novartis, in 2020.

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 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 web site at www.incyte.com.

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Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this release contain predictions, estimates and other forward-looking statements, including statements regarding whether or when ruxolitinib might be approved in the U.S. for patients with acute GVHD who have had an inadequate response to corticosteroids. 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 for the treatment of patients with acute GVHD who have had an inadequate response to corticosteroids, the results of additional data and additional analyses of data from the REACH1 study, actions taken by regulatory authorities, and other risks detailed from time to time in Incyte's reports filed with the Securities and Exchange Commission, including its Form 10-Q for the quarter ending September 30, 2018. Incyte disclaims any intent or obligation to update these forward-looking statements.

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