Incyte Announces Initiation of Pivotal Clinical Trial of Ruxolitinib (Jakafi®) for the Treatment of Essential Thrombocythemia

November 15, 2017

WILMINGTON, Del.--(BUSINESS WIRE)--Nov. 15, 2017-- Incyte Corporation (Nasdaq:INCY) today announced that the first patient has been treated in the RESET pivotal trial evaluating ruxolitinib (Jakafi®) compared to anagrelide for the treatment of patients with essential thrombocythemia (ET) who are resistant to or intolerant of hydroxyurea (HU).

“We are pleased to treat the first patient in our pivotal trial evaluating ruxolitinib as a treatment for ET, a rare blood cancer that can lead to life-threatening complications,” said Steven Stein, M.D., Chief Medical Officer, Incyte. “We look forward to building on the clinical evidence for ruxolitinib and to advancing this trial to help address the needs of higher-risk patients with ET, who are resistant to or intolerant of HU and currently have limited treatment options.”

ET is a rare, chronic blood cancer, part of a group of related blood cancers known as myeloproliferative neoplasms (MPNs), characterized by increased platelet production, a white cell count above the normal range, persistently elevated platelet counts with normal red blood cell mass and the absence of prominent bone marrow fibrosis.[1] An increased platelet count can increase the risk of thrombosis. Thrombosis can, in turn, lead to serious health problems including heart attack or stroke. Vascular complications and transformation to myelofibrosis (MF) or acute myeloid leukemia (AML) are the major causes of increased morbidity and mortality in patients with ET.[2,3]

About the RESET Study

The randomized, double-blind, double-dummy pivotal study (NCT03123588) is evaluating the safety and efficacy of ruxolitinib versus anagrelide as a treatment of patients with ET. The study is expected to enroll approximately 120 patients, 18 years or older, diagnosed with ET who are resistant to or intolerant of HU, with a screening platelet count of >650 × 10^9/L and white blood cell (WBC) count of >11.0 × 10^9/L.

The primary endpoint of this study is the proportion of patients who achieve platelet and WBC control over 1 year of follow-up. Key secondary endpoints include safety and tolerability and the proportion of patients who achieve complete remission (CR) or partial remission (PR). For more information about the study, please visit https://clinicaltrials.gov/ct2/show/NCT03123588.

About Jakafi® (ruxolitinib)

Ruxolitinib is a first-in-class JAK1/JAK2 inhibitor approved by the U.S. Food and Drug Administration, as Jakafi® (ruxolitinib), 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.

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 website 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 press release, including statements regarding the Company's expectations for the study evaluating ruxolitinib as a treatment for ET, contain predictions, estimates and other forward-looking statements. These forward-looking statements are based on the Company's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments and the risks related to the efficacy or safety of the Company's development pipeline, 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 and competitive and technological advances; and other risks detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, including its Form 10-Q for the quarter ended September 30, 2017. Incyte disclaims any intent or obligation to update these forward-looking statements.

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i Tefferi A, Thiele J, Orazi A, et al. Proposals and rationale for revision of the World Health Organization diagnostic criteria for polycythemia vera, essential thrombocythemia, and primary myelofibrosis: recommendations from an ad hoc international expert panel. Blood 2007;110:1092-109 7.

ii Passamonti F, Rumi E, Arcaini L, et al. Prognostic factors for thrombosis, myelofibrosis, and leukemia in essential thrombocythemia: a study of 605 patients. Haematologica 2008;93:1645-1651.

iii Besses C, Cervantes F, Pereira A, et al. Major vascular complications in essential thrombocythemia: a study of the predictive factors in a series of 148 patients. Leukemia 1999;13:150-154.

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