# Incyte Announces REACH1 Pivotal Trial Meets Primary Endpoint of Overall Response Rate for Ruxolitinib (Jakafi®) in Steroid-Refractory Acute Graft-Versus-Host Disease

June 21, 2018

*Results support planned sNDA submission in 2018*

WILMINGTON, Del.--(BUSINESS WIRE)--Jun. 21, 2018-- Incyte Corporation (Nasdaq:INCY)today announced positive topline results from its ongoing pivotal Phase 2 REACH1 trial evaluating ruxolitinib (Jakafi®) in combination with corticosteroids for the treatment of patients with steroid-refractory acute graft-versus-host disease (GVHD). The study met its primary endpoint, demonstrating an overall response rate (ORR) of 55 percent (n=39/71) at Day 28. In addition, the best overall response rate (BORR), the number of patients achieving a response at any time point during the study, was 73 percent (n=52/71). The most common treatment-emergent adverse events of any grade were anemia (61%), thrombocytopenia (61%) and neutropenia (56%).

Based on these data from REACH1, Incyte plans to file a Supplemental New Drug Application (sNDA) for the approval of ruxolitinib for the treatment of steroid-refractory acute GVHD with the U.S. Food and Drug Administration (FDA) during the third quarter of 2018.

“The results of the REACH1 study demonstrate the potential of ruxolitinib to meaningfully improve the outcomes of allogeneic transplant patients who develop steroid-refractory acute GVHD and further underscore the promise of JAK inhibition to advance the treatment of this potentially-devastating condition,” said Steven Stein, M.D., Chief Medical Officer, Incyte. “We look forward to sharing additional results from this study with the medical community, and to working with U.S. regulatory authorities to submit our supplementary new drug application seeking approval of ruxolitinib in this indication later this year.”

Full detailed results from the REACH1 study will be submitted for presentation at an upcoming scientific meeting.

GVHD is a condition that can occur after an allogeneic transplant (the transfer of genetically dissimilar blood stem cells) and is a significant cause of morbidity and mortality in transplant recipients. In GVHD, the donated bone marrow or peripheral blood stem cells view the recipient’s body as foreign and attack the body. There are two forms of GVHD, acute and chronic, which can affect multiple organ systems including the skin, gastrointestinal (digestive) tract and liver.

"As the use of allogeneic – or donor – transplants has increased, unfortunately so has the prevalence of GVHD, which is associated with first-year mortality ranging from 25 to 75 percent depending on the grade or progression of the disease,” said Madan Jagasia, M.D., M.B.B.S., M.S., Professor of Medicine; Chief, Section of Hematology-Stem Cell Transplant; and Co-leader, Translation Research and Interventional Oncology, Vanderbilt-Ingram Cancer Center, Vanderbilt University Medical Center. “Despite available therapies for acute GVHD, patients do not always respond, underscoring the need for new and innovative treatment options for these patients.”

The FDA previously granted ruxolitinib Breakthrough Therapy Designation for the treatment of steroid-refractory acute GVHD, designed to expedite the development and review of drugs for serious or life-threatening conditions, as well as Orphan Drug Designation for the treatment of GVHD, 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 REACH**

The REACH clinical trial program for ruxolitinib in steroid-refractory acute GVHD includes the Incyte-sponsored REACH1 study—a single-cohort, pivotal Phase 2 study (NCT02953678) evaluating ruxolitinib in combination with corticosteroids in patients with steroid-refractory acute GVHD. It also includes the collaborative Novartis-sponsored randomized pivotal Phase 3 studies in steroid-refractory acute GVHD (REACH2) and steroid-refractory chronic GVHD (REACH3), which are both underway; data are expected in 2019.

The primary endpoint of the REACH1 study is overall response rate at day 28. Key secondary endpoints include duration of response, overall response rate at day 14, 56 and 100, non-relapse mortality and safety. For more information about the study, please visit https://clinicaltrials.gov/show/NCT02953678.

**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 U.S. and by Novartis as Jakavi® (ruxolitinib) outside the U.S. Jakafi is a registered trademark of Incyte Corporation. Jakavi is a registered trademark of Novartis AG in countries outside the U.S.

**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 plans to present additional study data at an upcoming scientific meeting, the plan to file an sNDA for the approval of ruxolitinib for the treatment of steroid-refractory acute GVHD with the FDA by the end of 2018, and the potential of ruxolitinib to meaningfully improve the outcomes of allogeneic transplant patients who develop steroid-refractory acute GVHD. 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 scheduling and related issues with respect to upcoming scientific meetings, unanticipated developments in and risks related to the efficacy or safety of ruxolitinib for the treatment of steroid-refractory acute GVHD, 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 March 31, 2018. Incyte disclaims any intent or obligation to update these forward-looking statements.

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