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## Results of REACH1 Study of Ruxolitinib (Jakafi®) for the Treatment of Acute Graft-Versus-Host Disease Demonstrate Rapid and Durable Patient Benefit

December 3, 2018

- Updated data to be presented today at the 60<sup>th</sup> annual ASH meeting
- REACH1 study formed the basis of sNDA, now under Priority Review by the FDA

WILMINGTON, Del.--(BUSINESS WIRE)--Dec. 3, 2018-- Incyte Corporation (Nasdaq:INCY) announces updated results from its pivotal Phase 2 REACH1 study evaluating ruxolitinib (Jakafi®) in combination with corticosteroids as a treatment for patients with acute graft-versus-host disease (GVHD) who have had an inadequate response to corticosteroids. As previously announced, the study met its primary endpoint, demonstrating an overall response rate (ORR) of 55 percent (n=39/71) at Day 28, along with a best overall response rate (BORR) – patients achieving a response at any time point during the study – of 73 percent (n=52/71).

Many of the patients (68 percent) had Grade III or Grade IV disease at baseline, illustrative of an at-risk patient population, and responses were observed irrespective of grade or steroid refractory (SR) criteria. Responses to ruxolitinib were rapid and durable; the median time to response was seven days and the median duration of response (DOR) for patients who had a minimum of six months of follow-up was 345 days. Adverse events reported were consistent with the safety profile established in prior ruxolitinib studies, and in patients with SR acute GVHD.

These results are being presented at the American Society of Hematology (ASH) Annual Meeting 2018 in San Diego, California, in an oral session today, Monday, December 3, from 7:00 a.m. PT to 8:30 a.m. PT (Location: Manchester Grand Hyatt, Grand Hall A; Oral Session 722, Abstract #601).

"There are known limitations to currently available treatment approaches for patients with high-risk or relapsed hematologic malignancies who develop acute GVHD after an allogeneic stem cell transplant. Nearly half of acute GVHD patients do not achieve sustained responses with corticosteroid therapy, and there are no approved treatments for these patients," said Madan Jagasia, M.D., M.B.B.S., M.S., Professor of Medicine, Vanderbilt University Medical Center, Department of Medicine, Division of Hematology-Oncology and Chief Medical Officer, Vanderbilt-Ingram Cancer Center. "The REACH1 results being presented at ASH demonstrate the potential of ruxolitinib to deliver meaningful and sustained benefits to patients with this serious condition who, without an approved second-line treatment option, have few treatment options."

GVHD is a condition that can occur after an allogeneic transplant (the transfer of genetically dissimilar blood stem cells) where the donated bone marrow or peripheral blood stem cells view the recipient's body as foreign and attack the body, leading to significant morbidity and mortality in transplant recipients. There are two forms of GVHD, acute and chronic, which can affect multiple organ systems including the skin, gastrointestinal (digestive) tract and liver. Acute GVHD typically occurs within the first 100 days following an allogeneic transplant and is classified based on clinical and histological features. With acute GVHD, up to 40 percent of patients have severe disease, resulting in a 12-month survival of 50 percent or less.<sup>1</sup>

"The updated results of the REACH1 study being presented at ASH further illustrate the potential of JAK inhibition as a therapeutic option in GVHD, and specifically reinforce the durability of responses seen in acute GVHD patients treated with ruxolitinib," said Steven Stein, M.D., Chief Medical Officer, Incyte. "We are currently working with the FDA to facilitate the expedited review of the sNDA for ruxolitinib in steroid refractory acute GVHD, and, if approved, we believe ruxolitinib will provide an innovative treatment option for U.S. patients with this deadly disease."

### Key Findings from REACH1

The primary endpoint of the REACH1 study was overall response rate (ORR) at Day 28, defined as the proportion of patients having complete response (CR), very good partial response (VGPR) or partial response (PR). The key secondary endpoint was six-month duration of response (DOR, the time from first response to GVHD progression or death). At the six-month data cutoff (July 2, 2018), 71 patients had received at least one dose of ruxolitinib, and treatment was ongoing in 11 patients (16 percent).

Results from the primary analysis being presented at ASH show that in patients with steroid refractory (SR) acute GVHD who are treated with ruxolitinib in combination with corticosteroids, the primary endpoint of ORR was 55 percent (n=39/71), with responses observed irrespective of grade or SR criteria. This included 19 (27 percent) patients with CR, seven (10 percent) patients with VGPR and 13 (18 percent) patients with PR.

The median DOR among Day 28 responders who had a minimum of six months follow-up was 345 days (lower limit, 159 days), the key secondary endpoint. Event-free probability estimates for Day 28 responders at three and six months were 82 percent and 65 percent, respectively. The median time to first response was rapid (seven days). Additionally, most patients had sustained reductions in corticosteroid use over time, with more than half of patients on ruxolitinib at Day 28 (56 percent; n=24/43) demonstrating a ≥50 percent reduction from baseline in corticosteroid dose.

Additional secondary endpoints of the REACH1 study include non-relapse mortality, overall survival (OS) and the incidence and severity of adverse events (AE). Non-relapse mortality rates at six, nine and twelve months were 44 percent, 48 percent and 53 percent, respectively. Among all patients, median OS was 232 days.

The ruxolitinib AE profile was consistent with expectations for ruxolitinib and for patients with SR acute GVHD. The most common treatment-emergent adverse events (TEAEs) of any grade were anemia (65 percent), hypokalemia (49 percent), decreased platelet count (45 percent), peripheral edema (45 percent) and decreased neutrophil count (39 percent). A total of 14 patients had a cytomegalovirus (CMV) event (n=10, infection; n=4, viremia), and all patients who had a CMV event had a positive CMV donor or recipient serostatus or both at baseline. Fatal treatment-related TEAEs were sepsis and pulmonary hemorrhage (one patient each) and were attributed to both ruxolitinib and corticosteroids. No deaths were attributed to CMV events.

Data from the REACH1 study supported the submission of a supplemental New Drug Application (sNDA) by Incyte which was accepted for Priority Review by the U.S. Food and Drug Administration and assigned a Prescription Drug User Fee Act (PDUFA) date of February 24, 2019. The FDA grants Priority Review to medicines that have the potential to provide significant improvements in the treatment of a serious disease.

## About REACH

The REACH clinical trial program for Jakafi in patients with GVHD who have had an inadequate response to corticosteroids includes the Incyte-sponsored REACH1 study—a single-cohort, pivotal Phase 2 study (NCT02953678) evaluating Jakafi in combination with corticosteroids in patients with acute GVHD who have had an inadequate response to corticosteroids. For more information about the REACH1 study, please visit <https://clinicaltrials.gov/show/NCT02953678>.

The REACH clinical program also includes the collaborative Novartis-sponsored randomized pivotal Phase 3 studies in acute GVHD (REACH2) and chronic GVHD (REACH3), which are both underway; data are expected in 2019.

## 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](http://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](http://www.incyte.com).

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

## 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 the potential of ruxolitinib to benefit patients who develop acute GVHD, the durability of responses seen in acute GVHD patients treated with ruxolitinib, whether and when the Company's sNDA for the approval of ruxolitinib for the treatment of steroid refractory acute GVHD will be approved by the FDA, and whether ruxolitinib will become an accepted treatment option for such patients.

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 in and risks related to: unanticipated delays; further research and development and the results of clinical trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; determinations made by the FDA; the Company's dependence on its relationships with its collaboration partners; the efficacy or safety of the

Company's products and the products of the Company's collaboration partners; 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, 2018. The Company disclaims any intent or obligation to update these forward-looking statements.

<sup>1</sup> MacMillan *et al.* Biology of Blood and Marrow Transplantation. (2002). 8:387-394



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