Incyte Announces that the REACH2 Pivotal Trial of Ruxolitinib (Jakafi®) Meets Primary Endpoint in Patients with Steroid-Refractory Acute Graft-Versus-Host Disease

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- Results of randomized Phase 3 REACH2 trial show that ruxolitinib significantly improves overall response rate (ORR) at 28 days vs. best available therapy in patients with steroid-refractory acute graft-versus-host disease (GvHD)

- Full results expected to be submitted to an upcoming scientific meeting

WILMINGTON, Del.--(BUSINESS WIRE)--Oct. 16, 2019-- Incyte Corporation (Nasdaq:INCY) today announced positive results from the Novartis-sponsored pivotal Phase 3 REACH2 study evaluating ruxolitinib (Jakafi®) in patients with steroid-refractory acute graft-versus-host disease (GVHD). The study met its primary endpoint of improving overall response rate (ORR) at Day 28 with ruxolitinib treatment compared to best available therapy. No new safety signals were observed, and the ruxolitinib safety profile in REACH2 was consistent with that seen in previously reported studies in steroid-refractory acute GVHD.

Further analysis of the safety and efficacy data is ongoing. Novartis expects to initiate discussions with ex-U.S. regulatory authorities in 2020, and to submit REACH2 results for presentation at an upcoming scientific meeting.

“GVHD is a challenging and serious disease, and physicians around the world need access to therapies that can improve outcomes for patients,” said Peter Langmuir, M.D., Group Vice President, Targeted Therapies, Incyte. “This positive result of the REACH2 study is excellent news for patients as it further reinforces the potential of ruxolitinib as a treatment option that can provide meaningful results for patients with steroid-refractory acute GVHD.”

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

Earlier this year, Jakafi was approved by the U.S. Food and Drug Administration (FDA) for the treatment of steroid-refractory acute GVHD in adult and pediatric patients 12 years and older based on results of the REACH1 trial. Jakafi is marketed by Incyte in the U.S.; ruxolitinib (Jakavi®) is licensed to Novartis ex-U.S.

In addition, the pivotal REACH3 trial evaluating ruxolitinib in patients with steroid-refractory chronic GVHD is ongoing. A recent interim efficacy and safety analysis conducted by an Independent Data Monitoring Committee has recommended that REACH3, which is co-sponsored by Incyte and Novartis, should continue without modification. The results of the REACH3 trial are expected to be available in 2020.

About REACH2

REACH2 (NCT02913261) is a randomized, open-label, multicenter Phase 3 study sponsored by Novartis, evaluating safety and efficacy of ruxolitinib compared with best available therapy in patients with steroid-refractory acute GVHD.

The primary endpoint was overall response rate (ORR) at Day 28, defined as the proportion of patients demonstrating a best overall response (complete response or partial response). Secondary endpoints include durable ORR at Day 56, ORR at Day 14, duration of response, overall survival and event-free survival, among others. For more information about the study, please visit https://clinicaltrials.gov/ct2/show/NCT02913261.

About REACH

The REACH clinical trial program is evaluating Jakafi in patients with steroid-refractory GVHD and includes the collaborative Novartis-sponsored randomized pivotal Phase 3 trials: REACH2 and REACH3. The ongoing REACH3 trial is evaluating patients with steroid-refractory chronic GVHD with results expected next year. For more information about the REACH3 study, please visit https://clinicaltrials.gov/ct2/show/NCT03112603.

The REACH program was initiated with the Incyte-sponsored REACH1 trial, a prospective, open-label, single-cohort, multicenter, pivotal Phase 2 trial (NCT02953678) evaluating Jakafi in combination with corticosteroids in patients with steroid-refractory grade II-IV acute GVHD. For more information about the study, including trial results, please visit https://clinicaltrials.gov/show/NCT02953678.

About Jakafi® (ruxolitinib)

Jakafi is a first-in-class JAK1/JAK2 inhibitor approved by the U.S. FDA for treatment of steroid-refractory acute GVHD in adult and pediatric patients 12 years and older.

Jakafi is also indicated for treatment of polycythemia vera (PV) in adults who have had an inadequate response to or are intolerant of hydroxyurea as well as adults 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.

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: for certain types of MF and PV - low platelet count, low red blood cell count, bruising, dizziness, and headache; and for acute GVHD – low red blood cell counts, low platelet counts, low white blood cell counts, infections and fluid retention.

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, have a high level of fat in your blood (high blood cholesterol or triglycerides), 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.

Women should not take Jakafi while pregnant or planning to become pregnant. Do not breast-feed during treatment with Jakafi and for 2 weeks after the final dose.

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 whether and when the REACH2 data will be presented, when results from the REACH3 study will be available, and the effect of the REACH2 results on patients with GVHD, 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 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; the ability to enroll sufficient numbers of subjects in clinical trials; 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; the acceptance of the Company's products and the products of the Company's collaboration partners in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; greater than expected expenses; expenses relating to litigation or strategic activities; 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 June 30, 2019. The Company disclaims any intent or obligation to update these forward-looking statements.

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