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Incyte Announces Acceptance and Priority Review of sNDA for Jakafi® (ruxolitinib) as a Treatment for Patients with Chronic Graft-Versus-Host Disease

WILMINGTON, Del.--(BUSINESS WIRE)-- Incyte (Nasdaq:INCY) today announced that the U.S. Food and Drug Administration (FDA) has accepted for Priority Review the supplemental New Drug Application (sNDA) for ruxolitinib (Jakafi®) for treatment of steroid-refractory chronic graft-versus-host disease (GVHD) in adult and pediatric patients 12 years and older.

The sNDA submission is based on results from the Phase 3, randomized REACH3 study comparing ruxolitinib with best available therapy (BAT) in patients with steroid-refractory chronic GVHD. In the REACH3 study, which was recently presented at the 62nd American Society of Hematology (ASH) Annual Meeting & Exposition, patients treated with ruxolitinib experienced a significantly greater overall response rate (ORR) compared to BAT at Week 24, the primary endpoint (49.7% vs. 25.6%; p<0.0001). For the key secondary endpoints, ruxolitinib was associated with a longer median failure-free survival (FFS) than BAT at Week 24 (not reached vs. 5.7 months; hazard ratio (HR), 0.370; p<0.0001), and greater symptom improvement per the modified Lee Symptom Scale (mLSS) at Week 24 (24.2% vs. 11.0%; odds ratio (OR), 2.62; p=0.0011). The best ORR for patients receiving ruxolitinib was 76.4%. No new safety signals were observed, and adverse events were consistent with the known safety profile of ruxolitinib.

“Chronic GVHD is a life-threatening complication following stem cell transplant that burdens a vulnerable patient population, which today has limited treatment options,” said Peter Langmuir, M.D., Group Vice President, Oncology Targeted Therapies, Incyte. “The acceptance of this sNDA represents an important milestone for Incyte as we continue our work towards helping more people living with GVHD, particularly for those who do not respond to steroids. We look forward to working closely with the FDA to bring this innovative therapy to patients and to providing continued support to the GVHD community in the United States.”

GVHD is a condition that can occur after an allogeneic stem cell transplant (the transfer of stem cells from a donor) in which 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, which generally occurs within 100 days of transplant, and chronic, which generally occurs after 100 days of transplant1. Both forms can affect multiple organ systems, including the skin, gastrointestinal (digestive) tract and liver.

The FDA grants Priority Review to medicines that may offer a major advance in treatment where none currently exists. This designation shortens the review period to six months compared to 10 months for Standard Review. The Prescription Drug User Fee Act (PDUFA) target action date for Jakafi in steroid-refractory chronic GVHD is June 22, 2021.

The sNDA is also being reviewed as part of the Project Orbis program, an initiative of the U.S. FDA Oncology Center of Excellence that provides a framework for concurrent submission and review of oncology drugs among international regulatory agencies. Participating countries for this application include Canada, Australia, Switzerland, Brazil and the United Kingdom.

In 2019, Jakafiwas approved by the U.S. Food and Drug Administration for the treatment of steroid-refractory acute GVHD in adult and pediatric patients 12 years and older2.

About REACH3

REACH3 (NCT03112603), a randomized, open-label, multicenter Phase 3 study sponsored by Novartis and conducted in collaboration with and co-funded by Incyte, is evaluating the safety and efficacy of ruxolitinib compared with best available therapy in patients with steroid-refractory chronic GVHD.

The primary endpoint is overall response rate (ORR) at Week 24 (i.e., Cycle 7, Day 1), defined as the percentage of participants demonstrating a complete or partial response. Key secondary endpoints include failure-free survival (FFS) and change in the modified Lee Symptom Scale (mLSS) score at Week 24. Other secondary endpoints include best overall response (BOR), duration of response (DoR), overall survival (OS), and safety. For more information about the study, please visit **https://clinicaltrials.gov/ct2/show/NCT03112603**.

About REACH

The REACH clinical trial program evaluating ruxolitinib in patients with steroid-refractory GVHD includes the randomized pivotal Phase 3 REACH2 and REACH3 trials, conducted in collaboration with Novartis.

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 the treatment of polycythemia vera (PV) in adults who have had an inadequate response to or are intolerant of hydroxyurea, intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF in adults, and for the treatment of steroid-refractory acute GVHD in adult and pediatric patients 12 years and older.

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 or low red blood cell counts, bruising, dizziness, headache, and diarrhea; and for acute GVHD – low platelet, red or 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 is a Wilmington, Delaware-based, global biopharmaceutical company focused on finding solutions for serious unmet medical needs through the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit **Incyte.com** and follow **@Incyte**.

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 ongoing clinical development program for ruxolitinib, the REACH program and the Company's GVHD program generally, and whether and when ruxolitinib will be approved for use in the U.S. or elsewhere for steroid-refractory chronic GVHD or any other indication, 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 annual report on Form 10-K for the year ended December 31, 2020. The Company disclaims any intent or obligation to update these forward-looking statements.

1 Ferrara JL., et al. Graft-versus-host disease. Lancet. 2009;373(9674):1550-1561.
2 Jakafi (ruxolitinib) tablets: Prescribing Information. U.S. Food and Drug Administration; January 2020.

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Incyte Contacts:

Media:

Jenifer Antonacci
Senior Director, Public Affairs
Tel: +1 302 498 7036
jantonacci@incyte.com

Kristen Griffiths
Senior Manager, Public Affairs
Tel: +1 302 498 7012
kgriffiths@incyte.com

Investor:

Christine Chiou
Senior Director, Investor Relations
Tel: +1 302 274 4773
cchiou@incyte.com

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