Incyte Announces Plans to Initiate a Phase 3 Clinical Trial of Ruxolitinib (Jakafi®) as a Treatment for Patients with COVID-19 Associated Cytokine Storm

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- Incyte also intends to launch an Expanded Access Program in the United States to allow eligible patients with COVID-19 associated cytokine storm to receive ruxolitinib

- Incyte has an ample commercial and clinical supply of ruxolitinib in the U.S. and is increasing manufacturing efforts in response to the COVID-19 pandemic

WILMINGTON, Del.--(BUSINESS WIRE)--Apr. 2, 2020-- Incyte (Nasdaq:INCY) today announced the Company is working with the U.S. Food and Drug Administration (FDA) to initiate a Phase 3 clinical trial (RUXCOVID) to evaluate the efficacy and safety of ruxolitinib (Jakafi®) plus standard-of-care (SoC), compared to SoC therapy alone, in patients with COVID-19 associated cytokine storm. The collaborative study will be sponsored by Incyte in the United States and Novartis outside of the United States.

Additionally, given the urgent nature of the COVID-19 pandemic, Incyte intends to initiate a separate open-label emergency Expanded Access Program (EAP) in the United States. The protocol will allow eligible patients with severe COVID-19 associated cytokine storm to receive ruxolitinib while it is being investigated for this indication.

“Our intent is to build on emerging evidence from independent studies to further establish the role ruxolitinib could play in balancing immune response to the infection and therefore potentially improving outcomes of patients with COVID-19 associated cytokine storm,” said Steven Stein, M.D., Chief Medical Officer, Incyte. “We recognize the significant and urgent medical need of patients with severe COVID-19 infection, and we are working with the FDA in an effort to rapidly advance the RUXCOVID and EAP studies.”

In the interim, as the Phase 3 study and EAP protocols are awaiting potential approval by the FDA, questions or inquiries regarding the availability of ruxolitinib for compassionate use or independent research should be made to:

U.S. Medical Information
1-855-4MED-INFO (1-855-463-3463)
medinfo@incyte.com.

Ruxolitinib is a Janus kinase (JAK1/JAK2) inhibitor discovered by Incyte scientists. Overactive signaling through the JAK-STAT pathway has been associated with many types of cancer, including a group of rare blood cancers called myeloproliferative neoplasms (MPNs), as well as other serious immune-mediated conditions such as graft-versus-host disease (GVHD). Because many patients with severe respiratory disease (e.g., pneumonia) due to COVID-19 have features consistent with cytokine storm and increased activation of the JAK-STAT pathway, it is hypothesized that ruxolitinib may be able to play a role in treating these patients.

Independent investigators have expressed interest in studying the potential of ruxolitinib to mitigate some of the effects of severe COVID-19 infection, and we are aware of several ongoing independent studies and anecdotal results. However, currently, there is limited evidence on the safety or efficacy of ruxolitinib in the clinical treatment of COVID-19 and ruxolitinib is not currently FDA-approved for this use.

At present, there is ample commercial and clinical supply of ruxolitinib in the United States to meet the needs of U.S. patients receiving ruxolitinib in its approved indications, and those participating in global clinical trials. Incyte is increasing manufacturing efforts to respond to anticipated supply needs related to COVID-19 studies and is working closely with distribution partners to monitor the supply of ruxolitinib.

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, in adults with intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF 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 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 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 in patients with COVID-19, the enrollment, design, timing, efficacy and results of the RUXCOVID clinical trial program or any EAP study, whether and when the RUXCOVID or EAP studies will be approved by the FDA, whether ruxolitinib will become an approved or effective treatment option for any patients with COVID-19 infection, and whether commercial and clinical supply of ruxolitinib in the U.S. will continue to be sufficient to meet the current needs, 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: developments relating to the COVID-19 pandemic in the U.S. and around the world; 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 or other regulators; 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-K for the year ended December 31, 2019. The Company disclaims any intent or obligation to update these forward-looking statements.

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