Incyte Announces Initiation of Phase 3 RUXCOVID Study Evaluating Ruxolitinib (Jakafi®) as a Treatment for Patients with COVID-19 Associated Cytokine Storm

April 17, 2020

- Expanded Access Program allowing additional eligible patients with COVID-19 associated cytokine storm to receive ruxolitinib is also open for enrollment in the United States

WILMINGTON, Del.--(BUSINESS WIRE)--Apr. 17, 2020-- Incyte (Nasdaq:INCY) today announced the initiation of RUXCOVID, a global, randomized, double-blind, placebo-controlled Phase 3 clinical trial evaluating the efficacy and safety of ruxolitinib (Jakafi®) plus standard-of-care (SoC) in patients aged ≥12 years with COVID-19 associated cytokine storm. The collaborative study is sponsored by Incyte in the United States and Novartis outside of the United States.

The composite primary endpoint is the proportion of patients who die, develop respiratory failure (require mechanical ventilation) or require intensive care unit (ICU) care by Day 29. Secondary endpoints comprise various efficacy assessments including evaluation of clinical status using a 9-point ordinal scale; in-hospital outcomes (mortality rate; proportion of patients requiring mechanical ventilation; duration of hospitalization, ICU stay, supplemental oxygen, invasive mechanical ventilation); change in the National Early Warning Score (NEWS2); change in SpO_2/FiO_2 ratio; proportion of patients with no oxygen therapy (oxygen saturation of ≥94% on room air); and safety. RUXCOVID will enroll approximately 400 patients globally.

Additionally, given the urgent nature of the COVID-19 pandemic, Incyte is also initiating a separate 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.

“There is an unprecedented unmet medical need for treatments that prevent or reduce severe COVID-19 related complications to improve outcomes for patients and alleviate the overwhelming pressure on the global healthcare system,” said Steven Stein, M.D., Chief Medical Officer, Incyte. “We thank the FDA for the expedited review of the RUXCOVID study and hope to enroll this important clinical trial as quickly as possible to determine the potential utility of ruxolitinib for treatment of patients with severe COVID-19 associated cytokine storm.”

RUXCOVID is the first Phase 3, randomized, placebo-controlled study designed to evaluate the efficacy and safety of ruxolitinib in patients with COVID-19 associated cytokine storm.

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 clinical trials. Incyte is increasing manufacturing efforts to respond to anticipated supply needs related to COVID-19 studies and working closely with distribution partners to monitor the supply of ruxolitinib.

For more information about Incyte’s response to COVID-19, including information on the RUXCOVID study and EAP, visit: Incyte.com/COVID-19.

About COVID-19 Associated Cytokine Storm
Cytokine storm is a severe immune overreaction that can be triggered by a viral infection and can lead to serious complications, including pneumonia and acute respiratory distress syndrome (ARDS). Patients with COVID-19 associated cytokine storm who experience these complications often require intensive care, including intubation and the use of mechanical ventilation, and are at an increased risk of mortality.

Emerging evidence suggests that regulating overactive signaling through the JAK-STAT pathway during a cytokine storm associated with COVID-19 could be a potential treatment approach, and it is hypothesized that ruxolitinib, a JAK1/JAK2 inhibitor, may be able to play a role in treating these patients.

Currently, there is limited clinical evidence on the safety and efficacy of ruxolitinib for the treatment of COVID-19 associated cytokine storm, and ruxolitinib is not FDA-approved for this use.

About RUXCOVID
RUXCOVID is a global, randomized, double-blind, placebo-controlled, 29-day, multi-center Phase 3 study evaluating the efficacy and safety of ruxolitinib plus standard of care (SoC) therapy in patients aged ≥12 years with COVID-19 associated cytokine storm compared to placebo plus SoC therapy.

The composite primary endpoint is the proportion of patients who die, develop respiratory failure (require mechanical ventilation), or require intensive care unit (ICU) care by Day 29. Secondary endpoints are comprised of various efficacy assessments including evaluation of clinical status using a 9-point ordinal scale; in-hospital outcomes (mortality rate; proportion of patients requiring mechanical ventilation; duration of hospitalization, ICU stay, supplemental oxygen, invasive mechanical ventilation); change in the National Early Warning Score (NEWS2); change in SpO_2/FiO_2 ratio; proportion of patients with no oxygen therapy (oxygen saturation of ≥94% on room air); and safety.

Eligible patients will be randomized 2:1 to receive oral ruxolitinib 5mg twice daily (BID) or oral-matching placebo for a total of 14 days. Study treatment will be given in combination with SoC therapy according to the investigator’s clinical judgement. After 14 days of therapy, should clinical signs or symptoms not improve or worsen, and the potential benefit outweighs the potential risks, patients may receive an additional 14 days of study therapy. In total, patients will be followed on study for 29 days post-randomization.

The RUXCOVID study is sponsored by Incyte in the United States, and Novartis outside of the United States.

About the Ruxolitinib Expanded Access Program (EAP) in COVID-19
The ruxolitinib Expanded Access Program (EAP) in COVID-19 for patients with severe COVID-19 associated cytokine storm allows eligible patients to receive ruxolitinib while it is being investigated in COVID-19 patients. Patients must be unable to participate in other clinical trials of ruxolitinib in COVID-19 to qualify for this EAP.

For more information, please visit Incyte.com/COVID-19. Questions or inquiries regarding the EAP or independent research should be made to:

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

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 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 in patients with COVID-19, the enrollment, design, timing, efficacy and results of the RUXCOVID clinical trial program or any EAP study, 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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