Incyte Announces Results from the Phase 3 DEVENT Study Evaluating Ruxolitinib (Jakafi®) as a Treatment for Patients with COVID-19 Associated Acute Respiratory Distress Syndrome (ARDS) on Mechanical Ventilation

March 18, 2021

- Improvement in mortality for each dose compared to placebo, while trending toward positive, was not statistically significant for the overall study population

- Significant improvement in mortality seen in U.S. study participants at both doses, and in the overall population when data from both treatment arms was pooled

- Expanded Access Program to allow eligible patients in the United States with COVID-19 associated ARDS to receive ruxolitinib will be discussed with the U.S. Food and Drug Administration

WILMINGTON, Del.--(BUSINESS WIRE)-- Incyte (Nasdaq:INCY) today announced results from the Phase 3 DEVENT study evaluating the efficacy and safety of ruxolitinib (5mg and 15mg) plus standard of care (SoC) versus SoC in patients on mechanical ventilation with COVID-19 associated Acute Respiratory Distress Syndrome (ARDS), a type of respiratory failure characterized by rapid onset of widespread inflammation in the lungs.

While results indicate a trend towards an improvement in mortality in the overall study population (N=211), the DEVENT study did not meet its primary endpoint—mortality due to any cause through day 29—adjusted for ARDS severity between the two treatment arms versus placebo (55.2% vs. 74.3% [Odds Ratio (OR): 0.42 (95% CI: 0.171-1.023)], *P*=0.0280 in the 5mg arm and 51.8% vs. 69.6% [OR: 0.46 (95% CI: 0.201-1.028)], *P*=0.0292 in the 15mg arm). In the U.S. study population (N=191), which accounts for the majority (91%) of the DEVENT study patients, there was a clinically and statistically significant improvement in mortality in each of the 5mg (46.7% vs. 69.1% [OR: 0.39 (95% CI: 0.157-0.948)], *P*=0.0189) and 15mg treatment arms (47.1% vs. 66.7% [OR: 0.43 (95% CI: 0.188-0.974)], *P*=0.0215) versus placebo, respectively. Additionally, a post-hoc analysis of the overall study population pooling both the 5mg and 15mg ruxolitinib arms together versus placebo, showed a statistically significant improvement in mortality (53.6% vs. 70.7% [OR: 0.47 (95% CI: 0.219-0.996)], *P*=0.0244). More than half of study patients (55%) received remdesivir and 90% of study patients received corticosteroids prior to or during the study.

The safety profile was generally consistent with hospitalized patients with COVID-19 and consistent with treatment with ruxolitinib. The most common adverse events on the ruxolitinib arms, regardless of dose, compared to placebo were anemia (20.7% vs. 22.2%), increased alanine aminotransferase (ALT, 14.6% vs. 13.3%), increased aspartate transaminase (AST, 14.0% vs. 8.9%) and hypertension (11.6% vs. 11.1%), respectively.

“There remains a significant unmet medical need for treatments that may potentially improve survival outcomes for patients suffering from severe COVID-19 related complications, specifically those requiring mechanical ventilation,” said Steven Stein, M.D., Chief Medical Officer, Incyte. “We hope the results of this study, and the potential utility of ruxolitinib for treatment of patients with severe COVID-19 associated ARDS, will contribute to the advances being made across the scientific community to alleviate the burden this pandemic has placed on patients, as well as the healthcare system. We look forward to discussing the results of the DEVENT study with regulatory authorities in the United States.”

Given the urgent nature of the COVID-19 pandemic, Incyte plans to make ruxolitinib available to eligible patients in the United States at no cost via an Expanded Access Program (EAP) pending agreement with the U.S. Food and Drug Administration. The protocol will allow eligible patients with severe COVID-19 associated ARDS with disease severity requiring mechanical ventilation to receive ruxolitinib.

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 or the COVID-19 EAP.

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

About DEVENT (NCT04377620)

A Phase 3 randomized, double-blind, placebo-controlled, multicenter clinical trial, the DEVENT study evaluated the efficacy and safety of ruxolitinib 5mg and 15mg plus standard of care (SoC) compared to SoC plus placebo in patients with COVID-19 associated acute respiratory distress syndrome (ARDS) on mechanical ventilation. At initiation, the study aimed to enroll 500 patients; in December 2020, enrollment was stopped and the final analysis was conducted at the time of the planned interim analysis.

The primary endpoint of the study evaluated the mortality rate at day 29 of ruxolitinib 5mg twice daily (BID) plus SoC therapy and ruxolitinib 15mg BID plus SoC compared with placebo plus SoC, in participants with COVID-19 associated ARDS who required mechanical ventilation. Secondary outcomes measures included number of days patients were ventilator free, did not receive supplemental oxygen, did not use vasopressor therapy, as well as the number of days patients were out of the hospital, clinical status at Day 15 and 29 using the COVID-19 ordinal scale, change in organ function or rate of failure (as measured by Sequential Organ Failure Assessment or SOFA Score) and safety.

For more information about DEVENT, please visit: https://www.clinicaltrials.gov/ct2/show/NCT04377620.

About the Ruxolitinib Expanded Access Program (EAP) in COVID-19

The ruxolitinib Expanded Access Program (EAP) in COVID-19 will provide eligible patients with severe COVID-19 associated ARDS to receive ruxolitinib at no cost.

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 DEVENT 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, 2020. The Company disclaims any intent or obligation to update these forward-looking statements.

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