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

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- *Initial data show that treatment with ruxolitinib plus standard-of-care (SoC) did not prevent complications in patients with COVID-19 associated cytokine storm*

WILMINGTON, Del.--(BUSINESS WIRE)-- Incyte (Nasdaq:INCY) today announced that the Phase 3 RUXCOVID study evaluating the safety and efficacy of ruxolitinib (Jakafi®), a JAK1/JAK2 inhibitor, plus standard-of-care (SoC) as a treatment for patients 12 years and older with COVID-19 associated cytokine storm did not meet its primary endpoint. Initial data show that there was no reduction in the proportion of patients receiving ruxolitinib plus SoC who experienced severe complications including death, respiratory failure requiring mechanical ventilation or admission to the intensive care unit (ICU) care by Day 29, compared to SoC treatment alone (12.0% vs. 11.8% [OR: 0.91 [95% CI: 0.48-1.73], *P*=0.769, respectively)[1].

In addition, there was no clinically relevant benefit observed among secondary and exploratory endpoints, including mortality rate by Day 29 and time to recovery, defined as the first day a patient met the criteria for category 0 (Uninfected – No clinical or virological evidence of infection), 1 (Ambulatory – No limitation of activities), or 2 (Ambulatory – Limitation of activities) on the 9-point ordinal scale[1]. Ruxolitinib was generally well tolerated and no significant safety concerns were identified[1]. A comprehensive analysis including safety data is ongoing. The results of this study do not affect other ongoing non-COVID-19 related ruxolitinib clinical trials or approved uses of ruxolitinib.

“Given the urgent nature of the COVID-19 pandemic and the need for treatments for patients hospitalized with severe COVID-19 associated cytokine storm, the results of the RUXCOVID study are disappointing,” said Steven Stein, M.D., Chief Medical Officer, Incyte. “However, we hope that these findings will contribute to the scientific understanding of this complex disease and to the collective efforts of the biopharma industry to find solutions that improve outcomes for patients with COVID-19.”

The RUXCOVID study is complete. The data will be further analyzed to determine any potential impact on other studies of ruxolitinib in patients with COVID-19, and will be submitted for publication.

Ruxolitinib (Jakafi®) is approved by the U.S. Food and Drug Administration 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. It is marketed by Incyte in the United States; ruxolitinib (Jakavi®) is licensed to Novartis ex-U.S.

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. RUXCOVID study patients were selected based on having pulmonary infiltrates, elevated respiratory rate or hypoxemia.

About RUXCOVID

RUXCOVID (NCT04362137) was 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 study enrolled 432 patients globally, and randomization was stratified by geographic region[2].

The primary endpoint was the proportion of patients who died, or developed respiratory failure and required mechanical ventilation or required intensive care unit (ICU) care by Day 29. Secondary endpoints were 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[2].

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

The RUXCOVID study was sponsored by Incyte in the United States and Novartis outside of the United States. For more information, please visit: https://clinicaltrials.gov/ct2/show/NCT04362137.

To learn more about Incyte’s response to COVID-19, including information on the 369-DEVENT study, please visit Incyte.com/COVID-19.

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 analysis and publication of the RUXCOVID results 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, which risks are 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 September 30, 2020. The Company disclaims any intent or obligation to update these forward-looking statements.

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[1] Data on file.

[2] "A Phase 3 Randomized, Double-blind, Placebo-controlled Multi-center Study to Assess the Efficacy and Safety of Ruxolitinib in Patients With COVID-19 Associated Cytokine Storm (RUXCOVID)." ClinicalTrials.gov. 2020. https://clinicaltrials.gov/ct2/show/NCT04362137.

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Incyte
Media
Catalina Loveman
+1 302 498 6171
cloveman@incyte.com

Nupur Patel, PharmD
+1 302 498 5822
npatel@incyte.com

Investors
Michael Booth, DPhil
+1 302 498 5914
mbooth@incyte.com

Christine Chiou
+1 302 274 4773
cchiou@incyte.com

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