New Phase 3 Data Show Jakafi® (ruxolitinib) is Superior to Best Available Therapy in Patients with Polycythemia Vera (PV)

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- *62 percent of PV patients treated with Jakafi achieved hematocrit control without phlebotomy, compared to 18 percent of patients treated with best available therapy*
- *RESPONSE-2 data complements previous findings from RESPONSE, reinforcing Jakafi is effective in PV patients with or without an enlarged spleen*

WILMINGTON, Del.--(BUSINESS WIRE)--Jun. 10, 2016-- Incyte Corporation (Nasdaq: INCY) today announced new 28-week data from the Phase 3 RESPONSE-2 study of Jakafi® (ruxolitinib). The data show that Jakafi was superior to best available therapy (BAT) in maintaining hematocrit control (62.2% vs. 18.7%, respectively; *P*<0.0001)[1] without the need for phlebotomy in patients with inadequately controlled polycythemia vera (PV) resistant to or intolerant of hydroxyurea (HU) who did not have an enlarged spleen. The safety profile of Jakafi was consistent with previous studies. These findings were presented at the 21stCongress of the European Hematology Association (EHA) in Copenhagen, Denmark.

In RESPONSE-2, patients did not have an enlarged spleen, as assessed by physical examination at each study visit (spleen palpation), and a majority (70%) were previously treated with HU only, therefore considered to have less advanced disease. The remaining patients were treated with multiple lines of therapy (30%).[1]

“We are pleased with the RESPONSE-2 study results presented at EHA, which reinforce the superiority of Jakafi over best available therapy in achieving hematocrit control, without phlebotomy, in patients with inadequately controlled PV without enlarged spleens,” said Steven Stein, M.D., Incyte’s Chief Medical Officer. “These results are meaningful to patients with uncontrolled PV who have few other treatment options to help manage their disease.”

Additionally, the RESPONSE-2 study demonstrated that nearly five times more patients with PV achieved complete hematologic remission with Jakafi compared to BAT at 28 weeks (23.0% vs 5.3% respectively, p=0.0019). Patients taking Jakafi also experienced improvement in their PV symptoms compared to BAT (50% vs 7.7%, respectively). Overall, Jakafi was well tolerated. Findings from this study are consistent with data from the RESPONSE pivotal trial, which evaluated patients with inadequately controlled PV with an enlarged spleen.[1,2]

“A key treatment goal for patients with PV is to achieve and maintain hematocrit control, and compared to best available therapy, these results from the RESPONSE-2 study demonstrate the clinical benefits of Jakafi in PV patients with less advanced disease,” said lead study investigator Francesco Passamonti, M.D., the University of Insubria, Varese, Italy. “The results from RESPONSE-2, coupled with the previously reported results, support Jakafi as a second-line treatment option for patients with PV.”

About RESPONSE-2

RESPONSE-2 is a multi-center, open label, randomized, Phase 3 study evaluating the efficacy and safety of Jakafi versus BAT. The trial randomized 149 patients with PV who are resistant to or intolerant of HU, dependent on phlebotomy for hematocrit control and do not have an enlarged spleen. Patients were randomized 1:1 (74 and 75 patients were randomized to Jakafi and BAT respectively), by stratification (based on HU-resistance or intolerance) to receive either Jakafi (10 mg twice-daily) or BAT, which was defined as investigator selected monotherapy or observation only. The dose was adjusted as needed throughout the study.

About Polycythemia Vera

Polycythemia vera (PV) is a myeloproliferative neoplasm (MPN) and is typically characterized by elevated hematocrit, the volume percentage of red blood cells in whole blood, which can lead to a thickening of the blood and an increased risk of blood clots, as well as an elevated white blood cell and platelet count.[3] Patients with PV who fail to consistently maintain appropriate blood count levels, including appropriate hematocrit levels, have an approximately four times higher risk of major thrombosis (blood clots) or cardiovascular death.[4] Patients with PV can also suffer from an enlarged spleen and a significant symptom burden which may be attributed to thickening of the blood and lack of oxygen to parts of the body.[5] These symptoms commonly include fatigue, itching, night sweats, bone pain, fever, and weight loss.[6]

Approximately 100,000 patients in the U.S. are living with PV.[7] Current standard treatment for PV is phlebotomy (the removal of blood from the body) plus aspirin. When phlebotomy can no longer control PV, chemotherapy such as hydroxyurea, or interferon, is utilized.[8,9] Approximately one in four patients with PV are considered uncontrolled[10,11] because they have an inadequate response to or are intolerant of hydroxyurea, the most commonly used chemotherapeutic agent for the treatment of PV.

About Jakafi (ruxolitinib)

Jakafi is a first-in-class JAK1/JAK2 inhibitor approved by the U.S. Food and Drug Administration, for treatment of people with polycythemia vera (PV) who have had an inadequate response to or are intolerant of hydroxyurea.

Jakafi is also indicated for treatment of people with intermediate or high-risk myelofibrosis (MF), including primary MF, post–polycythemia vera MF, and post–essential thrombocythemia MF.

Jakafi is marketed by Incyte in the United States and by Novartis as Jakavi® (ruxolitinib) 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: low platelet count, low red blood cell counts, bruising, dizziness, headache.

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, 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. Do not drink grapefruit juice while on Jakafi.

Women should not take Jakafi while pregnant or planning to become pregnant, or if breast-feeding.

Full Prescribing Information, which includes a more complete discussion of the risks associated with Jakafi, is available at www.jakafi.com.

About Incyte

Incyte Corporation is a Wilmington, Delaware-based biopharmaceutical company focused on the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit the Company's website at www.incyte.com.

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Forward Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including statements regarding the long-term clinical benefits of treatment with Jakafi for patients with PV who do not have an enlarged, 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 and the risks related to the efficacy or safety of the Company's development pipeline, the results of further research and development, the high degree of risk and uncertainty associated with drug development, clinical trials and regulatory approval processes, other market or economic factors and competitive and technological advances; and other risks 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 March 31, 2016. Incyte disclaims any intent or obligation to update these forward-looking statements.

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