

## **Five-year Results from Phase 3 Study of Jakafi® (ruxolitinib) Show Sustained Overall Survival Benefit in Patients with Myelofibrosis (MF)**

June 6, 2016

*- COMFORT-I data demonstrate that treatment with Jakafi resulted in a 31 percent reduction in the risk of death and sustained durable spleen volume reduction in patients with MF*

*- These five-year data support previously published findings for Jakafi*

WILMINGTON, Del.--(BUSINESS WIRE)--Jun. 6, 2016-- Incyte Corporation (Nasdaq:INCY) today announces five-year data from the Phase 3 COMFORT-I study evaluating the long-term safety and efficacy of Jakafi® (ruxolitinib) in patients with intermediate-2 or high-risk myelofibrosis (MF). These follow-up results showed an overall survival (OS) benefit among patients treated with ruxolitinib with a 31 percent reduction in the risk of death (HR=0.69; 95% CI: 0.50, 0.96;  $P=0.025$ ) compared to patients randomized to placebo. Because the majority of patients on the placebo arm crossed over to receive ruxolitinib therapy (median 41.1 weeks after randomization), these data suggest that earlier treatment with ruxolitinib may be associated with improved long-term survival in patients with intermediate-2 or high-risk MF.

Additionally, over the five-year period, 59 percent (92/155) of patients who continued on treatment with ruxolitinib achieved at least a 35 percent reduction in spleen volume at any given time. The median duration of spleen response was 168.3 weeks. The mean spleen volume reduction from baseline at five years was 37.6 percent for patients who continued on treatment with ruxolitinib. After week 24, hemoglobin and platelet count remained stable through 5 years.

"Nearly, five years after the launch of Jakafi for the treatment of intermediate and high-risk MF, these findings provide important insight into the treatment's long-term clinical benefits," said Steven Stein, M.D., Incyte's Chief Medical Officer. "The overall survival benefit observed in the COMFORT-I study, along with sustained reductions in spleen volume, are meaningful for patients with this rare disease who often experience significant, debilitating symptoms, and even mortality, as a result of their disease."

These data are scheduled for presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting 2016 taking place June 3–7, 2016 in Chicago, Illinois.

"Previous findings from this study and overall survival trends reinforce the benefits of long-term treatment with ruxolitinib in patients with intermediate and high-risk MF. Achieving outcomes such as reduction in spleen volume is critical to the successful management of patients with this chronic and debilitating disease," said Ruben A. Mesa, M.D., FACP, Chair, Division of Hematology & Medical Oncology, Deputy Director, Mayo Clinic Cancer Center, Chair, Arizona Cancer Coalition, and Professor of Medicine.

### **Results from the COMFORT-I Study**

COMFORT-I, a randomized (1:1), double-blind, placebo-controlled Phase 3 study, compared the efficacy and safety of ruxolitinib to placebo in 309 patients with intermediate-2 or high-risk primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis.

Of the 155 patients randomized to ruxolitinib, 28 percent of patients were still on treatment at the time of this analysis (median follow-up 268 weeks). Of the 111 patients originally randomized to the placebo arm who crossed over to ruxolitinib (median 41.1 weeks after randomization), 25 percent remained on treatment at the time of this analysis (median follow-up 268 weeks).

Overall, 69 (45%) and 82 (53%) deaths were reported in the ruxolitinib and placebo arms, respectively. Median OS has not been reached for patients randomized to receive ruxolitinib.

Adverse events (AEs) were consistent with those reported in previous studies of ruxolitinib and there was no increase in the incidence of AEs with longer exposure to treatment.

COMFORT-I (Abstract #7012) is scheduled for presentation by Dr. Mesa on Monday, June 6, 2016, 8:00–11:30 a.m., E354b Hall A.

### **About Myelofibrosis (MF)**

MF is part of a group of related rare blood cancers known as myeloproliferative neoplasms (MPNs). In MF, a patient's bone marrow can no longer produce enough normal blood cells, causing the spleen and/or liver to enlarge.<sup>1</sup> MF is a progressive disease, which leads to bone marrow scarring and significant debilitating disease-related symptoms such as anemia, fatigue, and itching which can result in a poor quality of life.<sup>2</sup> Patients with MF have a decreased life expectancy, with an average survival of approximately five to six years.<sup>3</sup> The cause of MF is unknown but is linked to genetic mutations—between 50% and 60% of people with MF have a specific mutation of the Janus Kinase 2 gene (JAK2).<sup>4</sup>

### **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](http://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](http://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 intermediate or high-risk MF and the presentation of data regarding the Company's COMFORT-1 study, 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.

### References

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