Pooled Analysis of Five-Year Data from Two Phase 3 Studies Further Supports Overall Survival Advantage Observed in Patients with Myelofibrosis Treated With Jakafi® (ruxolitinib)

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- Long-term treatment with Jakafi prolonged survival compared to controls

- Data suggest that earlier treatment with Jakafi may improve survival advantage for patients with myelofibrosis (MF)

WILMINGTON, Del.--(BUSINESS WIRE)--Dec. 4, 2016-- Incyte Corporation (Nasdaq:INCY) today announces an exploratory pooled analysis of data from the five-year follow-up of the Phase 3 COMFORT-I and COMFORT-II trials which further supports previously published overall survival findings and suggests that earlier treatment with Jakafi® (ruxolitinib) may result in an improved survival advantage for patients with intermediate-2 or high-risk myelofibrosis (MF) than best available therapy (BAT) or placebo. These data also reinforce previous long-term results observed with ruxolitinib compared with controls (BAT or placebo).

“Understanding how earlier treatment with Jakafi may impact overall survival for appropriate patients with myelofibrosis is critical as physicians look to identify the most effective treatment approach for patients with this rare and debilitating disease,” said Peg Squier, M.D., Ph.D., Incyte’s Head of U.S. Medical Affairs.

The 5-year, intent-to-treat analysis of pooled data from two Phase 3 studies showed prolonged survival for patients with intermediate-2 or high-risk MF randomized to ruxolitinib, with the risk of death reduced by 30 percent for patients who received ruxolitinib compared with the control groups. Ruxolitinib also exhibited an overall survival (OS) advantage in various patient subgroup analyses including age, sex, disease type, risk status, JAK2V617F mutation status, baseline spleen length, anemia, white blood cell count, and platelet count. Additionally, using data-modeling techniques aimed at correcting for crossover delay, overall survival advantage was more pronounced for patients who were randomized to receive ruxolitinib at the start of the trial compared with patients who crossed over from control to ruxolitinib.

These data are scheduled for presentation today at the 58th American Society of Hematology (ASH) Annual Meeting 2016 taking place in San Diego, California.

Results from the COMFORT-I & COMFORT-II Pooled Analysis

The double-blind COMFORT-I trial and the open-label COMFORT-II trial were both randomized Phase 3 studies that evaluated the safety and efficacy of ruxolitinib in 528 patients with intermediate-2 or high-risk primary MF, post–polycythemia vera MF, or post–essential thrombocythemia MF. Across the pooled analysis, there were a total of 301 patients randomized to ruxolitinib (COMFORT-I, n=155; COMFORT-II, n=146), 227 to placebo in COMFORT-I (n=154) or to BAT in COMFORT-II (n=73).

In both COMFORT-I and COMFORT-II, patients were permitted to cross over to ruxolitinib from control treatment if they had progressive splenomegaly or a protocol-defined progression event. Crossover was mandatory following treatment unblinding in COMFORT 1. All continuing patients in the control arm in COMFORT II crossed over to ruxolitinib by the 3 year follow-up.

At the five-year intent-to-treat analysis, 42.5 percent (n=128) of the patients randomized to the ruxolitinib group died compared with 51.5 percent (n=117) of the patients randomized to the control group. Key findings include the following results:

- Median overall survival for ruxolitinib was 5.3 years compared with 3.8 years for the control group.
- Using a rank-preserving structural failure time modeling method, the OS advantage was more pronounced for patients originally randomized to ruxolitinib compared with patients who crossed over from control to ruxolitinib (median OS: ruxolitinib, 5.3 y; control, 2.3 y; HR, 0.35; 95% CI, 0.23–0.59), which suggests that the delay in ruxolitinib treatment may be the underlying reason for the difference in survival.

This analysis (Abstract #3110) is being presented as a part of a poster session (#634) on Sunday, December 4, 2016, 6:00-8:00 PM PST, Hall GH.

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.[1] 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.[2] Patients with MF have a decreased life expectancy, with an average survival of approximately five to six years.[3] 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).[4]

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 intermediate or high-risk myelofibrosis (MF), including primary MF, post–polycythemia vera MF, and post–essential thrombocythemia MF.

Jakafi is also indicated for treatment of people with polycythemia vera (PV) who have had an inadequate response to or are intolerant of hydroxyurea.

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: 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 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 September 30, 2016. Incyte disclaims any intent or obligation to update these forward-looking statements.

[1]Leukemia & Lymphoma Society. "Myelofibrosis Facts." Available at: http://www.lls.org/sites/default/files/file_assets/FS14_Myelofibrosis_Fact%20Sheet_Final9.12.pdf. Accessed November 2015.

[2] Mesa RA, Schwagera S, Radia D, et al. The Myelofibrosis Symptom Assessment Form (MFSAF): An Evidence-based Brief Inventory to Measure Quality of Life and Symptomatic Response to Treatment in Myelofibrosis. Leuk Res. 2009;33:1199-1203.

[3] Gangat N, Caramazza D, Vaidya R, et al. DIPSS-plus: A Refined Dynamic International Prognostic Scoring System (DIPSS) for Primary Myelofibrosis that Incorporates Prognostic Information from Karyotype, Platelet Count and Transfusion Status. J Clin Oncol. 2011; 29:392-397.

[4] Patriarca F, Bacigalupo A, Sperotto A, et al. Allogeneic hematopoietic stem cell transplantation in myelofibrosis: the 20-year experience of the Gruppo Italiano Trapianto di Midollo Osseo (GITMO). Haematologica. 2008; 93:1514-1522.

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