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Data Presented at 2013 ASCO Offers First Evidence that Long-Term Treatment with Jakafi® (ruxolitinib) May Stabilize or Reverse Bone Marrow Fibrosis, a Key Marker of Worsening Disease in Patients with Myelofibrosis

June 4, 2013

CHICAGO--(BUSINESS WIRE)--Jun. 4, 2013-- Incyte Corporation (Nasdaq: INCY) announced that results from an exploratory analysis of bone marrow fibrosis data from an ongoing Phase I/II single-arm, open-label clinical trial for Jakafi® (ruxolitinib) were presented today at the 2013 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago. Fibrosis of the bone marrow, a cardinal feature of myelofibrosis (MF), was shown to stabilize or reverse after 24 and 48 months of Jakafi treatment in the majority of patients with MF, a magnitude of an effect not seen with long-term treatment with hydroxyurea. Jakafi, an oral JAK1 and JAK2 inhibitor, is FDA-approved for the treatment of patients with intermediate or high-risk myelofibrosis.

"These results provide the first evidence of a drug therapy that may stabilize or improve bone marrow fibrosis and are encouraging because the only other proven option is bone marrow transplantation, which is a procedure with high risks. Future studies should improve our understanding of the significance of these findings," stated presenting author Hans Michael Kvasnicka, M.D., of the University of Frankfurt in Germany. According to Kvasnicka, additional research, including a European LeukemiaNet international initiative, is ongoing to better define the role of fibrosis in MF.

"Ruxolitinib has shown clinically meaningful results in symptom improvement and spleen reduction, and additional data has shown potential survival benefits. Now the findings from this exploratory analysis suggest that long-term therapy with ruxolitinib may positively impact another key underlying hallmark of this life-threatening and progressive disease," stated Srdan Verstovsek, M.D., Ph.D., Professor, Department of Leukemia, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center in Houston.

The results of the analysis were reported during an oral presentation, *Exploratory Analysis of the Effect of Ruxolitinib on Bone Marrow Morphology in Patients with Myelofibrosis*. The analysis evaluated long-term data of patients with MF who were treated with ruxolitinib (n=68) in a Phase I/II trial. Biopsies were obtained at baseline and at 24 (n=68) and 48 (n=18) months, and bone marrow fibrosis grade was determined by three expert hematopathologists using the World Health Organization scoring system and blinded to patient data and outcome. Stabilization or improvement of bone marrow fibrosis was observed at both time points, and by month 48, bone marrow fibrosis was stabilized in 56 percent of ruxolitinib-treated patients and improved in 22 percent. The percentage of ruxolitinib-treated patients with bone marrow fibrosis grade worsening at 24 and 48 months was 37 percent and 25 percent, respectively. In a separate database analysis of hydroxyurea-treated patients, it was shown that stabilization or reversal occurred in 41 percent and 10 percent of patients after 24 months (n=41) and in 44 percent and 0 percent of patients after 48 months (n=36); these results were consistent with previous studies¹. The percentage of hydroxyurea-treated patients with bone marrow fibrosis grade worsening at 24 and 48 months was 65 percent and 74 percent, respectively. While not a direct comparison, the two data analyses suggest bone marrow fibrosis grade worsening among hydroxyurea-treated patients at 48 months was nearly triple that seen in the ruxolitinib-treated patients.

The slides used during the presentation can be accessed at: [2013 ASCO - BM Fibrosis Presentation](#)

About Jakafi

Jakafi is a prescription medicine used to treat 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 may cause your platelet, red blood cell, or white blood cell counts to be lowered. 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 experience unusual bleeding, bruising, fatigue, shortness of breath, or a fever.

Infection: You may be at risk for developing a serious infection while taking Jakafi. Tell your healthcare provider if you develop symptoms such as chills, nausea, vomiting, aches, weakness, fever, or painful skin rash or blisters.

The most common side effects of Jakafi include dizziness and headache.

These are not all the possible side effects of Jakafi. Ask your healthcare provider or pharmacist 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 liver or kidney problems, are on dialysis, or have any other medical condition. Do not drink grapefruit juice while taking Jakafi.

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

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

About Myelofibrosis

Myelofibrosis (MF) is a life-threatening blood cancer that belongs to a group of diseases referred to as myeloproliferative neoplasms (or MPNs). MF has a poor prognosis and limited treatment options.^{2,3} While the exact prevalence of MF is uncertain, and estimates vary widely, based on extensive market research, Incyte estimates MF affects about 16,000 to 18,500 people in the U.S.⁴ The enlarged spleen and debilitating symptoms of MF are linked to dysregulated signaling in the Janus kinase (JAK) pathway. This dysregulation may be caused by various mechanisms and mutations, such as the JAK2 V617F mutation.^{5,6} Although allogeneic stem cell transplantation may cure myelofibrosis, the procedure is associated with significant morbidity and transplant-related mortality and is available to less than 5 percent of patients who are young and fit enough to undergo the procedure.⁷

About Incyte

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

Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including without limitation statements with respect to the potential efficacy and therapeutic and commercial value of Jakafi (ruxolitinib), including that long-term treatment with Jakafi may stabilize or reverse bone marrow fibrosis in patients with myelofibrosis, that additional data showed potential survival benefits, and that the findings from the exploratory analysis suggest that ruxolitinib, over the course of long-term therapy, may positively impact another key underlying hallmark of this life-threatening and progressive disease, that the two data analyses suggest bone marrow fibrosis grade worsening among hydroxyurea-treated patients at 48 months was more than triple that seen in the ruxolitinib-treated patients, and statements with respect to future studies improving our understanding of the significance of these findings, contain predictions and estimates and are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995.

These forward-looking statements are based on Incyte'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 the efficacy or safety of Jakafi, the results of further research and development, other market or economic factors and technological advances, and other risks detailed from time to time in Incyte's filings with the Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the quarter ended March 31, 2013. Incyte disclaims any intent or obligation to update these forward-looking statements.

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