Incyte Drug Jakafi® (ruxolitinib) Improved Overall Survival in Phase III Trial of Patients with Myelofibrosis

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- *New three-year COMFORT-II study data presented at the European Hematology Association (EHA) meeting show that patients treated with Jakafi experienced sustained reductions in spleen size and a 52 percent reduction in the risk of death relative to patients treated with best available therapy*
- *COMFORT-II data also show that Jakafi continues to be well-tolerated after three years of treatment*
- *Results from a Phase I/II study also presented at EHA offer evidence that long-term treatment with Jakafi may stabilize or reverse bone marrow fibrosis, a key marker of worsening disease in patients with myelofibrosis*

STOCKHOLM--(BUSINESS WIRE)--Jun. 16, 2013-- Incyte Corporation (Nasdaq: INCY) today announced results from two ongoing clinical trials of Jakafi® (ruxolitinib), an oral JAK1 and JAK2 inhibitor that is FDA-approved for the treatment of patients with intermediate or high-risk myelofibrosis (MF), that were presented at the 18thCongress of the European Hematology Association (EHA) in Stockholm, Sweden. In a three-year follow-up analysis of the Phase III COMFORT-II study, treatment with Jakafi, which is marketed as Jakavi® by Novartis outside the United States, was associated with improved overall survival and sustained reductions in spleen size compared to best available therapy. In a separate exploratory analysis of bone marrow fibrosis data from an ongoing Phase I/II single-arm, open-label clinical trial, by 48 months of treatment, Jakafi stabilized or reversed fibrosis of the bone marrow in 56 percent and 22 percent, respectively, of patients with MF, a magnitude of an effect not seen historically with best available therapy.

“Results of these studies represent the continuing evolution in our understanding of the clinical benefits of Jakafi for patients with intermediate or high-risk myelofibrosis and further support my confidence that long-term treatment with Jakafi may modify this progressive and life-threatening blood cancer,” 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.

“Data from the Phase I/II study provide the first evidence that long-term treatment with Jakafi may stabilize or improve bone marrow fibrosis, a key marker of worsening disease in patients with myelofibrosis. These findings, in addition to what was presented at ASCO, provide a result not seen before with best available therapy, including hydroxyurea. 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.

Long-Term Outcomes from a Phase III Study Comparing Ruxolitinib with Best Available Therapy for the Treatment of Myelofibrosis: A 3-Year Update of COMFORT-II

In a three-year follow-up analysis of the COMFORT-II study, an overall survival advantage was observed in patients treated with Jakafi compared to patients receiving best available therapy. A 52 percent reduction in risk of death was observed in the Jakafi arm compared with best available therapy (HR=0.48; 95% CI, 0.28-0.85; p=0.009)[1], and the estimated probability of overall survival was significantly greater with Jakafi compared to best available therapy (81 percent compared to 61 percent, respectively) at 144 weeks. Additionally, 51.4 percent of patients treated with Jakafi achieved a ≥35 percent reduction from baseline in spleen size over the course of the study. Spleen response was maintained, with the median duration of this response not yet reached in the study.

Anemia and thrombocytopenia were the most common adverse events over the three-year follow-up; however, the rates of these events decreased over time. Among patients randomized to Jakafi and included in the extension phase, the general frequency of the most common non-hematologic adverse events (peripheral edema, diarrhea and asthenia) did not change over time.

The results are consistent with previous COMFORT-II and COMFORT-I study analyses, which demonstrate that Jakafi provides significant clinical benefits over best available therapy and placebo for patients suffering from intermediate or high-risk myelofibrosis.

The slides used during the presentation can be accessed at: EHA 2013 - 3-Year COMFORT-II Presentation

Long-Term Intervention Effects on Bone Marrow Morphology in Myelofibrosis: Patients Treated With Ruxolitinib and Best Available Therapy

Data were presented from an exploratory analysis that evaluated long-term data of patients with MF who were treated with Jakafi (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. Separate samples were also collected from a multicenter observational database from three European Union countries (160 biopsies in a cohort of 139 patients) in patients treated with best available therapy at 24 months (n=97) and 48 months (n=63)[9]. Additional research is needed to understand the clinical impact of these findings.

The slides used during the presentation can be accessed at: EHA 2013 - Bone Marrow Fibrosis Presentation

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 the 5 percent of patients who are young and fit enough to undergo the procedure.[7]

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. 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 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.incyte.com, which includes a more complete discussion of the risks associated with Jakafi.

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 treatment with Jakafi may stabilize or reverse bone marrow fibrosis in patients with myelofibrosis, that Jakafi may provide a survival advantage, and that long-term treatment with Jakafi may modify this progressive and life-threatening blood cancer, 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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References

1. Vannucchi, A, et al. Long-Term Outcomes From A Phase 3 Study Comparing Ruxolitinib With Best Available Therapy (BAT) For The Treatment of Myelofibrosis (MF): A 3 Year Update of Comfort II. Abstract #S1111.18th Congress of European Hematology Association (EHA). Stockholm, Sweden.

2. Kvasnicka, HM, et al. Long Term Intervention Effects on Bone Marrow Morphology in Myelofibrosis: Patients Treated With Ruxolitinib and Best Available Therapy. Abstract #S591.18th Congress of European Hematology Association (EHA). Stockholm, Sweden.

3. Cervantes F, et al. New prognostic scoring system for primary myelofibrosis based on a study of the International Working Group for Myelofibrosis Research and Treatment. Blood. 2009;113:2895-2901.

4. Gangat N, et al. DIPSS Plus: a refined dynamic international prognostic scoring system for primary myelofibrosis that incorporates prognostic information from karyotype, platelet count, and transfusion status. J Clin Oncol. 2011;29(4):392-397.

5. Data on File. Incyte Corporation.

6. Levine RL, Pardanani A, Tefferi A, Gilliland DG. Role of JAK2 in the pathogenesis and therapy of myeloproliferative disorders. Nat Rev Cancer. 2007;7:673-683.

7. Vannucchi AM, Guglielmelli P, Tefferi A. Advances in understanding and management of myeloproliferative neoplasms. CA Cancer J Clin. 2009;59:171-191.

8. 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(10):1514-1522.

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