Jakafi® (ruxolitinib) Continues to Show Improved Overall Survival for Patients with Myelofibrosis in Further Analyses of Phase III Data Presented at 2013 ASH

December 9, 2013

- ***Data from multiple presentations, including three-year follow-up analysis from COMFORT-I and a pooled analysis of the two COMFORT trials, suggest that patients treated with Jakafi maintained reductions in spleen volume and had improved survival over placebo and best available therapy***
- ***A separate retrospective analysis suggests that Jakafi treatment may reduce the risk of death by approximately 50 percent compared to conventional treatments***
- ***An exploratory analysis of data collected over five years in the ongoing Phase II trial offers evidence that Jakafi may stabilize or improve bone marrow fibrosis in patients with myelofibrosis***

NEW ORLEANS--(BUSINESS WIRE)--Dec. 9, 2013-- Incyte Corporation (Nasdaq: INCY) announced today that more than 35 analyses from clinical studies of Jakafi® (ruxolitinib) were presented at the 2013 American Society of Hematology (ASH) Annual Meeting from Dec. 7 to 10 in New Orleans. Jakafi, an oral JAK1/JAK2 inhibitor, is FDA-approved for the treatment of patients with intermediate or high-risk myelofibrosis (MF).

“Myelofibrosis is a debilitating, life-threatening blood cancer with limited treatment options. It is, therefore, rewarding to see that the expanding body of clinical data for Jakafi shows durable reductions in spleen volume and clinically meaningful improvements in health-related quality of life measures and supports a survival benefit for patients,” stated Paul A. Friedman, M.D., Incyte’s Chief Executive Officer and President.

Ruben Mesa, M.D., Deputy Director, Mayo Clinic Cancer Center; Chair, Division of Hematology and Medical Oncology, Mayo Clinic in Arizona; and creator of the Myelofibrosis Symptom Assessment Form, an evidence-based tool used in the COMFORT trials to measure quality of life and symptomatic response to treatment, stated, “Given the growing evidence of a potential survival benefit for Jakafi-treated patients, it’s important to note that data from COMFORT-I suggest that dose titration and close monitoring of blood counts early in the course of Jakafi treatment are more likely to help patients remain on drug therapy, achieve and maintain improvements in spleen volume and symptoms, and improve survival.”

Highlights of Key Data Presented

- Verstovsek, S, et al. *Long-term outcomes of ruxolitinib therapy in patients with myelofibrosis: 3-year update from COMFORT-I*.

  After a median three-year follow-up of patients in COMFORT-I, ruxolitinib treatment continued to maintain the previously reported reductions in spleen volume and improvements in quality of life measures. Overall survival favored patients originally randomized to ruxolitinib over those originally randomized to placebo (HR=0.69; 95% CI: 0.46-1.03; *P*=0.067). Additionally, because of the early crossover design in COMFORT-I, at the time of this analysis, patients originally randomized to placebo had been on ruxolitinib therapy a median of approximately two years, more than twice as long as their median time on placebo. Analyses were presented to show that because of the longer time these patients received Jakafi than placebo, the magnitude of the survival benefit observed may be underestimated relative to a comparison of ruxolitinib to a true placebo.

  Consistent with the results previously reported from the median two-year follow-up, new or worsening grade 3 or 4 anemia and thrombocytopenia occurred early in the course of treatment and then decreased in frequency with longer-term therapy. In addition, there was no apparent change in the frequency or severity of new or worsening non-hematologic adverse events over time.

  The slides used during the presentation can be accessed at: ASH 2013 - Verstovsek.

- Vannucchi, A, et al. *A pooled overall survival analysis of the COMFORT studies: 2 randomized Phase III trials of ruxolitinib for the treatment of myelofibrosis*.

  In a pooled analysis of COMFORT-I and COMFORT-II, intermediate-2– and high-risk patients randomized to treatment with ruxolitinib had significantly prolonged survival compared to those randomized to placebo or best available therapy (HR = 0.65; 95% CI, 0.46-0.90; P = .01). Additionally, patients with high-risk myelofibrosis who were initially randomized to treatment with ruxolitinib had an estimated survival similar to patients with intermediate-2-risk myelofibrosis in the control group. Further analysis that corrects for the early crossover to ruxolitinib suggests that the survival benefit may be

underestimated because patients in the placebo and best available therapy arms could cross over to receive ruxolitinib therapy. The authors also suggest that the survival benefit observed with ruxolitinib may be the result of multiple treatment effects, such as spleen volume reduction, improvement in symptoms, and improvement in nutritional status, which warrants further study.

The poster for this presentation can be accessed at ASH 2013 - Vannucchi.

Other data related to Jakafi presented at ASH include:

- Passamonti F, et al. *Impact of Ruxolitinib on the Natural History of Patients with Primary Myelofibrosis: a Retrospective Comparison of the DIPSS and the COMFORT-II Cohorts*

  An overall survival analysis was conducted, comparing ruxolitinib-treated patients with primary MF from the COMFORT-II study with patients in the Dynamic International Prognostic Scoring System (DIPSS) database. The cohort in the DIPSS database represents a multi-center group receiving conventional treatments. Consistent with the findings from the three-year follow-up analysis from COMFORT-I and the pooled analysis of COMFORT-I and COMFORT-II data, overall survival favored ruxolitinib over conventional therapy. In this analysis, ruxolitinib treatment appeared to reduce the risk of death by approximately one-half compared to conventional treatments (HR =0.51; 95% CI: 0.30-0.88).

  The poster for this presentation can be accessed at ASH 2013 - Passamonti.

- Kvansnicka HM, et al. *Effects of Five Years of Ruxolitinib Therapy on Bone Marrow Morphology in Patients With Myelofibrosis and Comparison with Best Available Therapy*

  An exploratory analysis of bone marrow morphology over five years in 68 patients from the ruxolitinib Phase II study suggests that ruxolitinib may stabilize or improve bone marrow fibrosis in patients with myelofibrosis. A higher percentage of ruxolitinib-treated patients showed stabilization or improvement of bone marrow fibrosis at 24, 48, and 60 months compared to a separate historical control cohort of patients treated with best available therapy. The authors concluded that results from this analysis strongly suggest that sustained JAK1/JAK2 inhibition may be disease-modifying in myelofibrosis. Additional studies are needed to determine the clinical impact of this finding.

  The poster for this presentation can be accessed at ASH 2013 - Kvansnicka.

- Mesa RA, et al. *Optimizing Dose Titration of Ruxolitinib: The COMFORT-I Experience*

  The objective of this analysis was to identify baseline patient characteristics for the selection of patients who may benefit from closer monitoring and dose titration after initiation of ruxolitinib therapy, based on findings from COMFORT-I. This analysis evaluated predictors of early dose reductions or anemia events in ruxolitinib-treated patients from the COMFORT-I trial. The authors concluded that a baseline platelet count less than 150×10^9/L or baseline hemoglobin less than 10 g/dL may be useful parameters to identify patients who are likely to require dose adjustments early in the course of ruxolitinib therapy.

  The poster for this presentation can be accessed at ASH 2013 - Mesa.

About Jakafi® (ruxolitinib)

Jakafi is an oral, selective inhibitor of Janus kinases 1 and 2 (JAK1 and JAK2). Jakafi is indicated for treatment of patients with intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF. This life-threatening blood cancer is characterized by bone marrow failure, enlarged spleen (splenomegaly) and debilitating symptoms.

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

Jakafi is marketed as Jakavi® by Novartis outside the United States. COMFORT-I was conducted by Incyte in the United States, Canada and Australia. COMFORT-II was conducted by Novartis in Europe.

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 contained herein, the matters set forth in this press release, including statements with respect to the potential efficacy, safety and therapeutic value of Jakafi® (ruxolitinib), including statements regarding an overall survival benefit or improvement or reduction in risk of death with treatment with Jakafi and that certain data may underestimate the survival benefit, that data from COMFORT-I suggest that dose titration and close monitoring of blood counts early in the course of Jakafi treatment are more likely to help patients remain on drug therapy, achieve and maintain improvements in spleen volume and symptoms, and improve survival, that treatment with Jakafi may stabilize or improve bone marrow fibrosis in patients with myelofibrosis, and that sustained JAK1/JAK2 inhibition may be disease-modifying in myelofibrosis, 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, the high degree of risk and uncertainty associated with drug development and clinical trials, 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 September 30, 2013. Incyte disclaims any intent or obligation to update these forward-looking statements.

Links to third party websites or pages are provided for convenience only. Each website is subject to its own terms of use, and Incyte encourages you to consult these policy statements. Incyte has no control over third party sites and does not endorse or recommend these sites, and expressly disclaims any responsibility for the accuracy of content or opinions set forth in any third party website or your use of that information.

Source: Incyte Corporation

Incyte Corporation
Pamela M. Murphy
Vice President, Investor Relations & Corporate Communications
(302) 498-6944