

New Data for Jakafi® (ruxolitinib) Presented at the 2012 American Society of Hematology Annual Meeting

December 10, 2012

- ***In long-term results from two randomized Phase III clinical trials (COMFORT-I and COMFORT-II), patients with myelofibrosis treated with Jakafi had improved survival over placebo and best available therapy, suggesting an overall survival benefit***
- ***Data from an ongoing Phase II trial suggest that long-term treatment with Jakafi may be a durably efficacious therapy for patients with polycythemia vera***

Incyte to host a webcast for investors featuring key results on Monday, Dec. 10, at 8:45 p.m. EST

ATLANTA--(BUSINESS WIRE)--Dec. 10, 2012-- Incyte Corporation (Nasdaq: INCY) announced today that several analyses from clinical studies of Jakafi® (ruxolitinib) were presented at the 2012 American Society of Hematology (ASH) Annual Meeting from Dec. 8 to 11 at the Georgia World Congress Center in Atlanta. Jakafi, an oral Janus kinase (JAK) inhibitor, is FDA-approved for the treatment of patients with intermediate or high-risk myelofibrosis (MF).

Of 24 Jakafi-related abstracts accepted for presentation at ASH, six are oral presentations. Two of the oral presentations highlight long-term results from both COMFORT-I and COMFORT-II in which patients with MF treated with Jakafi had improved survival over placebo and best available therapy, suggesting an overall survival benefit in patients with intermediate or high-risk MF. Additionally, data from this longer-term two-year follow-up show that improvements in quality of life measures and reductions in spleen volume were maintained with continued treatment.

Other data presented at ASH include results from a three-year follow-up of patients with polycythemia vera (PV) in a Phase II study, showing that ruxolitinib treatment resulted in durable response rates by modified European Leukemia Net criteria and improvements in PV-related symptoms.

"The long-term data for Jakafi continue to demonstrate tangible benefits for patients with myelofibrosis, including better management of this progressive and debilitating disease and an apparent improvement in overall survival," 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. "In addition, the three-year results from the Phase II trial of ruxolitinib in patients with polycythemia vera who are resistant to or intolerant of hydroxyurea are promising, and I look forward to seeing the Phase III data and the potential to use ruxolitinib to treat patients with PV."

"In addition to the promising overall survival data from the two COMFORT trials, exploratory analyses of the COMFORT-I trial provided additional guidance on dose titration. We're confident this information will help physicians find the optimal dose for each patient and maintain long-term treatment with Jakafi, providing the potential for longer survival," said Richard Levy, M.D., Incyte's Chief Drug Development and Medical Officer.

Highlights of Key Data Presented

- Verstovsek, S, et al. *Long-term outcome of ruxolitinib treatment in patients with myelofibrosis: Durable reductions in spleen volume, improvements in quality of life, and overall survival advantage in COMFORT-I.*
- Cervantes, F, et al. *Long-term safety, efficacy, and survival findings from COMFORT-II, a Phase III study comparing ruxolitinib with best available therapy for the treatment of myelofibrosis.*

In two Phase III randomized clinical studies, COMFORT-I and COMFORT-II, Jakafi was associated with a survival advantage over placebo and best available therapy, respectively. In COMFORT-I, reductions in spleen volume continued to be observed over two years of treatment. Spleen volume was reduced by 32 percent at week 24 with Jakafi treatment, and this reduction was sustained through week 96. Improvements in quality of life measures also continued to be observed over two years of treatment. Additionally, rates of grade 3 or 4 anemia and thrombocytopenia decreased with long-term therapy, and there was no apparent change in the frequency or severity of non-hematologic adverse events.

Survival analyses were conducted at a two-year follow-up in COMFORT-I and COMFORT-II, comparing patients randomized to Jakafi with those randomized to placebo and best available therapy, respectively. In COMFORT-I, Jakafi continued to be associated with a survival advantage over placebo. There were 27 deaths in the group treated with Jakafi, and 41 in the placebo group, representing a HR=0.58 (95% CI, 0.36-0.95; P = 0.028). Overall survival favored treatment with Jakafi regardless of JAK2V617F mutation status. Similarly, an updated analysis of COMFORT-II suggested longer survival for patients randomized to Jakafi when compared to those randomized to best available therapy. In this study, where twice as many patients were randomized to Jakafi (146) as to placebo (73), there were 14 percent (n=20) deaths in the group treated with Jakafi and 22 percent (n=16) in the best available therapy group, representing a HR=0.51 (95% CI, 0.26-0.99; P = 0.041). These survival benefits were observed even though all patients in the placebo and best available therapy groups continuing in the COMFORT studies were switched to Jakafi treatment soon after the primary analyses, suggesting that earlier initiation of treatment with Jakafi may have contributed to longer survival.

The slides used during the presentations can be accessed at: [2012 ASH Oral_Verstovsek_C-I](#) and [2012 ASH Oral_Cervantes_C-II](#).

- Verstovsek, S, et al. *Long-term efficacy and safety results from a Phase II study of ruxolitinib in patients with polycythemia vera.*

In a Phase II clinical trial of patients (n=34) with polycythemia vera (PV) who are resistant or intolerant to hydroxyurea, ruxolitinib treatment resulted in

clinical benefit by providing durable overall response rates by modified European Leukemia Net criteria as well as ameliorating symptoms commonly associated with PV, such as itching, night sweats and bone pain. Overall response was achieved in 97 percent of patients at week 24. Of these responders, 74 percent maintained overall response at week 144. Anemia and thrombocytopenia (primarily grade 1) were the most common adverse events.

The slides used during the presentation can be accessed at: [2012 ASH Oral_Verstovsek_PV](#).

Other data related to Jakafi presented orally at ASH include:

- Talpaz, M, et al. *Efficacy, hematologic effects, and dose of ruxolitinib in myelofibrosis patients with low starting platelet counts ($50\text{--}100 \times 10^9/\text{L}$): A comparison to patients with normal or high starting platelet counts*. [2012 ASH Oral Talpaz](#)
- Harrison, C, et al. *EXPAND: a Phase 1b, open-label, dose-finding study of ruxolitinib in patients with myelofibrosis and baseline platelet counts between $50 \times 10^9/\text{L}$ and $99 \times 10^9/\text{L}$* . [2012 ASH Oral Harrison](#)
- Vannucchi, A, et al. *Reductions in JAK2 V617F allele burden with ruxolitinib treatment in COMFORT-II, a Phase III study comparing the safety and efficacy of ruxolitinib with best available therapy*. [2012 ASH Oral Vannucchi](#)

The following presentations related to Jakafi were exhibited during poster sessions at ASH:

- Mesa, R, et al. *Clinical benefits of ruxolitinib therapy in myelofibrosis patients with varying degrees of splenomegaly and symptoms*. [2012 ASH Poster #1727](#)
- Mesa, R, et al. *Improvement in weight and total cholesterol and their association with survival in ruxolitinib-treated patients with myelofibrosis from COMFORT-I*. [2012 ASH Poster #1733](#)
- McMullin, M, et al. *The use of erythropoietic-stimulating agents with ruxolitinib in patients with primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis*. [2012 ASH Poster #2838](#)
- Verstovsek, S, et al. *Effect of ruxolitinib on the incidence of splenectomy in patients with myelofibrosis: A retrospective analysis of data from ruxolitinib clinical trials*. [2012 ASH Poster #2847](#)
- Ouagari, K, et al. *Cost-effectiveness of ruxolitinib versus best-available therapy for medical treatment of myelofibrosis: Canadian societal perspective*. [2012 ASH Poster #4255](#)
- Barosi, G, et al. *An individual patient supply program for ruxolitinib for the treatment of patients with primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis*. [2012 ASH Poster #2844](#)

About the Webcast

Incyte will host an investor meeting to discuss the new Jakafi data being presented at ASH. The presentation will be webcast live at 8:45 p.m. EST on December 10, 2012, and can be accessed at www.incyte.com under Investor Relations, Events and Webcasts. A replay of the event will be available for 60 days.

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.

Important Safety Information

- Treatment with Jakafi can cause hematologic adverse reactions, including thrombocytopenia, anemia and neutropenia, which are each dose-related effects, with the most frequent being thrombocytopenia and anemia. A complete blood count must be performed before initiating therapy with Jakafi. Complete blood counts should be monitored as clinically indicated and dosing adjusted as required. The three most frequent non-hematologic adverse reactions were bruising, dizziness and headache
- Patients with platelet counts $<200 \times 10^9/\text{L}$ at the start of therapy are more likely to develop thrombocytopenia during treatment. Thrombocytopenia was generally reversible and was usually managed by reducing the dose or temporarily withholding Jakafi. If clinically indicated, platelet transfusions may be administered
- Patients developing anemia may require blood transfusions. Dose modifications of Jakafi for patients developing anemia may also be considered
- Neutropenia ($\text{ANC} <0.5 \times 10^9/\text{L}$) was generally reversible and was managed by temporarily withholding Jakafi
- Patients should be assessed for the risk of developing serious bacterial, mycobacterial, fungal and viral infections. Active serious infections should have resolved before starting Jakafi. Physicians should carefully observe patients receiving Jakafi for signs and symptoms of infection (including herpes zoster) and initiate appropriate treatment promptly

- A dose modification is recommended when administering Jakafi with strong CYP3A4 inhibitors or in patients with renal or hepatic impairment [see *Dosage and Administration*]. Patients should be closely monitored and the dose titrated based on safety and efficacy
- There are no adequate and well-controlled studies of Jakafi in pregnant women. Use of Jakafi during pregnancy is not recommended and should only be used if the potential benefit justifies the potential risk to the fetus
- Women taking Jakafi should not breast-feed. Discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother

For Full Prescribing Information for Jakafi, visit www.Jakafi.com.

About the Incyte-Novartis Worldwide Collaboration and License Agreement

In 2009, Incyte entered into a worldwide collaboration and license agreement with Novartis. Incyte retained exclusive rights for the development and potential commercialization of ruxolitinib in all hematology-oncology indications in the US. Novartis received exclusive rights to the development and potential commercialization of ruxolitinib in all hematology-oncology indications outside of the US. Incyte received FDA approval of Jakafi for the treatment of patients with intermediate or high-risk myelofibrosis in November 2011, and in August 2012 Novartis announced that ruxolitinib, marketed as Jakavi® outside the United States, received approval from the European Commission for the treatment of disease-related splenomegaly or symptoms in adult patients with primary MF, post-polycythemia vera MF or post-essential thrombocythemia MF.

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 that there may be an overall survival benefit, or advantage or improvement with treatment with Jakafi, that earlier initiation of treatment with Jakafi may contribute to longer survival, that additional guidance on dose titration may provide information to help physicians find the optimal dose for each patient and maintain long-term treatment with Jakafi, providing the potential for longer survival, and the potential use of ruxolitinib to treat patients with polycythemia vera, 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 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, 2012. Incyte disclaims any intent or obligation to update these forward-looking statements.

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Source: Incyte Corporation

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