

New Data for Jakafi® (ruxolitinib) Presented at 2012 ASCO Annual Meeting

June 4, 2012

- **Data from an ongoing trial suggest a dosing strategy with Jakafi that may be efficacious and well-tolerated in myelofibrosis patients with low platelet counts**
- **Further analysis of adverse events from Phase III data in COMFORT-I indicates there is no withdrawal syndrome after discontinuation of therapy with Jakafi**
- **Phase III data from COMFORT-II provide further evidence that patients with myelofibrosis experience symptoms and reduced quality of life similar to patients with certain other severe cancers**

CHICAGO--(BUSINESS WIRE)--Jun. 4, 2012-- Incyte Corporation (Nasdaq: INCY) announced today that analyses from several clinical studies of Jakafi® (ruxolitinib) were presented at the 2012 American Society of Clinical Oncology Annual Meeting from June 1 to 5. Jakafi, an oral JAK1 and JAK2 inhibitor, is FDA-approved for the treatment of patients with intermediate or high-risk myelofibrosis (MF), and is the first and only product to be approved by the FDA for MF. Jakafi is also the first JAK inhibitor to be approved for any indication.

Highlights of Key Data Presented

- Talpaz, M, et al. *Preliminary safety and efficacy of ruxolitinib in patients with primary and secondary myelofibrosis with platelet counts of 50–100 x 10⁹/L*. Poster #6630

An interim analysis of an ongoing clinical study explored the safety and efficacy of Jakafi in 41 patients with MF who have baseline platelet counts between 50 X 10⁹/L and 100 X 10⁹/L prior to the start of therapy with Jakafi. A dosing strategy starting with 5 mg twice daily with subsequent dose optimization resulted in reductions in spleen size and improvements in MF-related symptoms at 24 weeks in most patients. Reductions in platelet counts during therapy were managed with dose reductions and interruptions. At the time of this analysis, the majority of patients had optimized their dose to 10 mg twice daily or higher. These data suggest a dosing strategy that may be efficacious and well-tolerated in patients with MF who have low platelet counts.

A copy of the Talpaz et al. poster presentation is available via the following link: [ASCO Poster #6630](#)

- Verstovsek, S, et al. *Adverse events and the return of myelofibrosis-related symptoms after interruption or discontinuation of ruxolitinib therapy*. Poster #6624

A further analysis of COMFORT-I data was conducted to evaluate the return of symptoms and assess adverse events (AEs) upon interruption or discontinuation of treatment with Jakafi. MF-related symptoms returned to baseline levels over the course of approximately seven days after stopping therapy, and this response was not dependent on the dose at which interruption occurred. Grade 3 or 4 and serious AEs did not differ in frequency or characterization from events observed in patients discontinuing placebo, demonstrating that discontinuation of Jakafi does not lead to a withdrawal syndrome.

A copy of the Verstovsek et al. poster presentation is available via the following link: [ASCO Poster #6624](#)

- Kiladjian, J, et al. *Health-related quality of life and symptom burden in patients with myelofibrosis in the COMFORT-II study*. Poster #6626

An analysis of the baseline health-related quality of life (HRQoL) and symptoms among patients enrolled in COMFORT-II provides further evidence that patients with myelofibrosis (MF) experience severe disease-related symptoms and have diminished HRQoL similar to patients with acute myeloid leukemia (AML), chronic myeloid leukemia (CML) and breast cancer. Patients with MF have the added burden of living with this reduced quality of life for many years.

A copy of the Kiladjian et al. poster presentation is available via the following link: [ASCO Poster #6626](#)

Other data related to Jakafi presented at ASCO include:

- Vannucchi, A, et al. *Reductions in JAK2V617F allele burden with ruxolitinib treatment in COMFORT-II, a phase III study comparing the safety and efficacy of ruxolitinib to best available therapy*. [Poster #6514](#)
- Harrison, C, et al. *Association of cytokine levels and reductions in spleen size in COMFORT-II, a phase III study comparing*

ruxolitinib to best available therapy. [Poster #6625](#)

The following posters about trials in progress were also presented at ASCO:

- le Coutre, P. *An open-label, multicenter, expanded access study assessing the safety and efficacy of oral ruxolitinib administered to patients with primary myelofibrosis, post-polycythemia myelofibrosis or post-essential thrombocythemia myelofibrosis.* [Poster #TPS6640](#)
- Gisslinger, H. *A phase Ib, open-label, dose-finding study of ruxolitinib in patients with primary myelofibrosis, post-polycythemia vera-myelofibrosis or post-essential thrombocythemia-myelofibrosis and baseline platelets 50 to <100 x 10⁹/L.* [Poster #TPS6642](#)
- Verstovsek, S. *RESPONSE: A randomized, open-label, phase III study of ruxolitinib in polycythemia vera patients resistant to or intolerant of hydroxyurea.* [Poster #TPS6643](#)

Indication, Usage and Dosing

Jakafi is indicated for treatment of patients with intermediate or high-risk myelofibrosis, including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF. Intermediate and high-risk MF patients include anyone over the age of 65 or who have or have had any of the following: anemia, constitutional symptoms, elevated white blood cell or blast counts or platelet counts less than 100 X 10⁹/L.^{1,2}

The recommended starting dose is based on the patient's platelet count. Dosage should be adjusted based on safety and efficacy. A blood cell count must be performed before initiating therapy with Jakafi and complete blood counts should be monitored every 2-4 weeks until doses are stabilized.

For more information and complete prescribing information, visit www.Jakafi.com.

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 less than 200 X 10⁹/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 (ANC <0.5 X 10⁹/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.

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.¹ 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.³ 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 JAK2V617F mutation.^{4,5}

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 approval from the FDA of Jakafi for the treatment of patients with intermediate or high-risk myelofibrosis on Nov. 16, 2011.

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 Jakafi® (ruxolitinib), including the potential efficacy, safety and therapeutic value of Jakafi, 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, 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, 2012. Incyte disclaims any intent or obligation to update these forward-looking statements.

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References

1. 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.
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4. 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.
5. Vannucchi AM, Guglielmelli P, Tefferi A. Advances in understanding and management of myeloproliferative neoplasms. *CA Cancer J Clin*. 2009;59:171-191.



Source: Incyte Corporation

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