First FDA-Approved Treatment for Myelofibrosis, Jakafi™ (ruxolitinib), Discussed in Multiple Presentations at 2011 ASH Annual Meeting

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Incyte to host a webcast for investors featuring these results on Monday, December 12 at 7:00 p.m. PT

SAN DIEGO--(BUSINESS WIRE)--Dec. 12, 2011-- Incyte Corporation (Nasdaq:INCY) today announced that further analyses from the global, pivotal Phase III clinical program of Jakafi (ruxolitinib or INC424) are being presented at the 2011 American Society of Hematology (ASH) Annual Meeting. The presentations include:

Verstovsek S, et al. *Consistent benefit of ruxolitinib over placebo in spleen volume reduction and symptom improvement across subgroups and overall survival advantage: results from COMFORT-I*. Abstract 278

Harrison C, et al. *Ruxolitinib provides reductions in splenomegaly across subgroups: an analysis of spleen response in the COMFORT-II study.* Abstract 279

Mesa R, et al. *Associations between improvements in myelofibrosis (MF) symptoms and quality of life measures with splenomegaly reduction in COMFORT-I: a randomized, double-blind, phase III trial of the JAK1 and JAK2 inhibitor ruxolitinib versus placebo in patients with MF.* Abstract 3842

Harrison C, et al. *Health-related quality of life and symptoms in myelofibrosis patients treated with ruxolitinib versus best available therapy.* Abstract 795

Jakafi was recently approved by the US Food and Drug Administration (FDA) for the treatment of intermediate or high-risk myelofibrosis, a potentially life-threatening blood cancer characterized by bone marrow failure, enlarged spleen (splenomegaly) and debilitating symptoms that can severely impact quality of life. Jakafi, an oral JAK1 and JAK 2 inhibitor, is the first and only product to be approved by the FDA for this disease. Jakafi is the first in a new class of drugs, known as JAK-inhibitors, to be approved for any indication.

Summary of Key Findings to be Presented

Regarding the survival analysis (Abstract 278), at the time of a planned safety update in the COMFORT-I study (median follow-up of 51 weeks), there were 13 (8.4%) deaths in the Jakafi group and 24 (15.7%) in the placebo group (HR=0.50; 95% CI, 0.25-0.98). These data are being presented by Srdan Verstovsek, M.D., Ph.D., Associate Professor, Department of Leukemia, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center and the principal investigator of the COMFORT-I pivotal trial.[1]

“These findings are consistent with an analysis comparing patients treated with Jakafi at our institution in the Phase II trial (INCB18424-251) with a matched historical control group, and collectively suggest the potential of this new agent to change the clinical course of myelofibrosis,” said Dr. Verstovsek.[2]

Treatment with Jakafi led to reductions in spleen volume and improvements in MF-related symptoms across multiple COMFORT-I subgroups evaluated, including MF subtype (primary MF, post-polycythemia vera MF or post-essential thrombocythemia MF), age, IPSS risk category (high-risk and intermediate-2), hemoglobin level, spleen size, symptom score, and JAK2V617F mutation status.[1] These findings were consistent with an analysis from the COMFORT-II trial comparing Jakafi to best available therapy.[3]

Additional presentations at ASH from COMFORT-I and COMFORT-II described improvements in patient-reported quality of life (QOL) measures associated with Jakafi therapy.[4,5]

COMFORT-I was conducted by Incyte. COMFORT-II was conducted by Novartis.

The most common adverse reactions in both studies were thrombocytopenia and anemia. These events were manageable and rarely led to discontinuation of Jakafi treatment. The most common non-hematologic adverse reactions were bruising, dizziness, and headache. Adverse events observed during treatment interruption showed no evidence of a withdrawal effect.

Please see Important Safety Information below, and the full Prescribing Information for Jakafi at www.jakafi.com or www.incyte.com.

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 10^9/L.[6,7]

The recommended starting dose for most patients is either 15 mg or 20 mg given orally twice daily 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.

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 10^9/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 10^9/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 potentially life-threatening blood cancer that belongs to a group of diseases referred to as myeloproliferative neoplasms (or MPNs). MF has a poor prognosis including debilitating symptoms and limited treatment options.[6] While the exact prevalence of MF is uncertain, and estimates vary widely, based on extensive market research, Incyte believes MF affects about 16,000 to 18,500 people in the U.S.[8]

About the Incyte-Novartis Collaboration

In 2009, Incyte entered into a worldwide collaboration and license agreement with Novartis. Incyte retained exclusive rights for the development and commercialization of ruxolitinib (INCB424) in the United States. Novartis received exclusive rights to the development and potential commercialization of ruxolitinib in all hematology-oncology indications outside of the United States.

About the Webcast

Incyte will host a webcast for investors at the ASH meeting on Monday, December 12 at 7:00 p.m. PT. During the webcast, Dr. Verstovsek and Dr. Harrison will review the data presented during the ASH sessions. The live webcast can be accessed by going to Incyte's website at www.incyte.com under Investor Relations, Events and Webcasts. A replay of the webcast will also be available following the event.

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 web site 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 having the potential to change the clinical course of myelofibrosis, are all 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 acceptance of Jakafi in the marketplace, risks related to market competition, risks and uncertainties associated with sales, marketing and distribution requirements, 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, 2011. Incyte disclaims any intent or obligation to update these forward-looking statements.

References

1. Verstovsek S, et al. Consistent benefit of ruxolitinib over placebo in spleen volume reduction and symptom improvement across subgroups and overall survival advantage: results from COMFORT-I. American Society of Hematology 2011 Annual Meeting (abstract 278).

2. COMFORT-I was not designed nor powered to demonstrate a statistically significant difference in overall survival within the timeframe of the study endpoint, Patients who remain in COMFORT-I continue to be followed.

3. Harrison C, et al. Ruxolitinib provides reductions in splenomegaly across subgroups: an analysis of spleen response in the COMFORT-II study. American Society of Hematology 2011 Annual Meeting (abstract 279).

4. Mesa R, et al. Associations between improvements in myelofibrosis (MF) symptoms and quality of life measures with splenomegaly reduction in COMFORT-I: a randomized, double-blind, phase III trial of the JAK1 and JAK2 inhibitor ruxolitinib versus placebo in patients with MF. American Society of Hematology 2011 Annual Meeting (abstract 3842).

5. Harrison CN, et al. Health-related quality of life and symptoms in myelofibrosis patients treated with ruxolitinib versus best available therapy. American Society of Hematology 2011 Annual Meeting (abstract 795).

6. 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.

7. 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.

8. Data on File. Incyte Corporation.

Source: Incyte Corporation

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