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FDA Approves Incyte's Jakafi(TM) (ruxolitinib) for Patients with Myelofibrosis

November 16, 2011

- First and Only FDA-Approved Treatment For Potentially Life-Threatening Blood Cancer

- Product Available Next Week; Incyte Establishes Comprehensive Patient Assistance Program

- Conference Call Scheduled, Today at 12:30 PM ET

WILMINGTON, Del.--(BUSINESS WIRE)--Nov. 16, 2011-- Incyte Corporation (Nasdaq: INCY) today announced that the U.S. Food and Drug Administration (FDA) has granted marketing approval for Jakafi™ (ruxolitinib) for the treatment of patients with intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF. Patients with intermediate and high-risk MF represent 80 to 90 percent of MF patients. Jakafi (JAK-ah-fye) is the first and only product to be approved by the FDA for MF, and the first in a new class of drugs, known as JAK inhibitors, to be approved for any indication. Jakafi is an oral JAK1 and JAK2 inhibitor.



Jakafi(TM) (ruxolitinib) is the first and only product to be approved by the FDA for myelofibrosis, and the first in a new class of drugs, known as JAK inhibitors, to be approved for any indication. (Photo: Business Wire)

"The availability of Jakafi is a significant medical advancement for people living with myelofibrosis, a debilitating disease," stated Paul A. Friedman, M.D., President and Chief Executive Officer of Incyte. "This milestone marks a tremendous achievement for Incyte because a scientific

discovery from our research laboratories has become the first JAK inhibitor to reach the market and provide a clinical benefit to patients."

MF is a progressive, potentially life-threatening blood cancer with limited treatment options.¹ Patients with MF suffer a high disease burden characterized by bone marrow failure, enlarged spleen (splenomegaly) and debilitating symptoms including fatigue, severe itching (pruritus), night sweats, bone pain, and early satiety (a feeling of fullness), leading to impaired quality of life.² The enlarged spleen and debilitating symptoms of MF are linked to dysregulated signaling in the Janus kinase (JAK) pathway.^{3,4}

"Today's FDA approval of Jakafi has the potential to transform the way we treat myelofibrosis," said 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. "In this Phase III clinical trial, we observed significant reductions in spleen size and significant improvements in symptoms. Importantly, these benefits were achieved early on, most within a month, and tended to be durable during treatment. In contrast, most of the patients who received placebo saw their spleens increase and their symptoms worsen."

"We are very excited about the first FDA approval of a treatment for MF. Not only is this a new therapy, but it brings additional education, awareness and attention to a profoundly debilitating disease," stated Robert Rosen, President of MPN Research Foundation.

Phase III Clinical Trial Data

The FDA approval was based on results from two randomized Phase III trials (COMFORT-I and COMFORT-II), which demonstrated that patients treated with Jakafi experienced significant reductions in splenomegaly (enlarged spleen). COMFORT-I also demonstrated improvements in symptoms as measured by the modified Myelofibrosis Symptom Assessment Form (MFSAF) v.2.0 electronic diary and the MFSAF Total Symptom Score (TSS) comprised of six specific symptoms (abdominal discomfort, pain under the left ribs, an early feeling of fullness, night sweats, bone and muscle pain and itching) all of which contributed to the overall benefit. Most patients taking placebo experienced worsening of these same parameters.

The COMFORT-I trial, conducted by Incyte, compared Jakafi to placebo in 309 patients with primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF. The trial met the primary endpoint, showing that 41.9% of patients treated with Jakafi experienced a 35% or greater reduction in spleen volume at 24 weeks, compared with 0.7% of patients taking placebo ($p < 0.0001$). A 35% reduction in spleen volume correlates to approximately a 50% reduction in spleen size on palpation. At week 24, the percentage of patients with a greater than or equal to 50% improvement in the TSS was 45.9% and 5.3% in patients treated with Jakafi and placebo, respectively ($p < 0.0001$), with a median time to response of less than four weeks.

The COMFORT-II trial, conducted by Novartis, Incyte's collaboration partner outside of the U.S., compared Jakafi to best available therapy in 219 patients with primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF. This trial also met the primary endpoint, showing that 28.5% of patients treated with Jakafi experienced a 35% or greater reduction in spleen volume at 48 weeks, compared with 0% of patients in the best available therapy arm ($p < 0.0001$).

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.

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 $100 \times 10^9/L$.^{1,5}

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 $200 \times 10^9/L$ 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 ($ANC < 0.5 \times 10^9/L$) 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.

Patient Assistant Program: IncyteCARES

Incyte has established IncyteCARES (Connecting to Access, Reimbursement, Education and Support), a comprehensive program that provides reimbursement support and educational resources for patients. Incyte is committed to providing financial assistance for patients in need who qualify for the available support programs. A toll-free number has been established to provide support regarding benefit verification, prior authorization and assistance with appeals. IncyteCARES also offers patient educational materials, resources and access to trained nurse professionals to answer questions regarding the program.

Jakafi will be available in the United States next week through a number of specialty pharmacies. Patients can access information about Jakafi and the IncyteCARES program by calling 1-855-4-Jakafi (855-452-5234) or visiting www.jakafi.com.

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 and limited treatment options.¹ 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.⁶

About the MPN Research Foundation

The primary mission of the MPN Research Foundation is to promote, fund and support the most innovative and effective research into the causes, treatments, and potentially the cure for essential thrombocythemia, polycythemia vera and myelofibrosis. For more information, go to <http://www.mpnresearchfoundation.org/>.

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.

Conference Call Information

Incyte will hold a conference call today at 12:30 PM ET to discuss the FDA approval of Jakafi, its price, and Incyte's patient assistance program. To access the conference call, please dial 877-407-8037 for domestic callers or 201-689-8037 for international callers. When prompted, provide the conference identification number, 383585.

If you are unable to participate, a replay of the conference call will be available for thirty days. The replay dial-in number for the U.S. is 877-660-6853 and the dial-in number for international callers is 201-612-7415. To access the replay you will need the conference account number 278 and the identification number 383585.

The conference call will also be webcast live and can be accessed at www.incyte.com under Investor Relations, Events and Webcasts.

About Incyte

Incyte Corporation is a Wilmington, Delaware-based biopharmaceutical company focused on developing and commercializing proprietary small molecule drugs for oncology and inflammation. For additional information on Incyte, please visit 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 transform the way physicians treat myelofibrosis and Jakafi being available in the United States next week through a number of specialty pharmacies, 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, risks associated with Incyte's dependence on its third party manufacturers 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.

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6. Data on File. Incyte Corporation.

Photos/Multimedia Gallery Available: <http://www.businesswire.com/cgi-bin/mmg.cgi?eid=50075108&lang=en>



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