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Incyte Announces EU Regulatory Milestone for Ruxolitinib

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WILMINGTON, Del., Apr 20, 2012 (BUSINESS WIRE) --Incyte Corporation (Nasdaq: INCY) announced today a European Union (EU) regulatory milestone from Novartis. The milestone includes a \$40 million payment earned based on the recommendation by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) for approval of ruxolitinib for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis. A second payment of \$60 million would be earned once Novartis achieves reimbursement and pricing approval in specific EU countries.

Ruxolitinib was approved by the US Food and Drug Administration (FDA) in November 2011 and is the first and only JAK inhibitor to have received regulatory approval. Ruxolitinib is known as Jakafi(TM) (ruxolitinib) in the US and will be called Jakavi(TM) in Europe.

In the EU, the European Commission generally follows the recommendations of the CHMP. The decision will be applicable to all 27 EU member states.

Indication, Usage and Dosing for Jakafi in the United States

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. 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 $100 \times 10^9/L$.^{1,2}

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 about Jakafi and for complete prescribing information, visit www.jakafi.com.

Important Safety Information for Jakafi

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.

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 November 16, 2011.

About Incyte

Incyte Corporation is a Wilmington, Delaware-based biopharmaceutical company focused on discovering, developing and commercializing proprietary small molecule drugs for oncology and inflammation. For additional information on Incyte, please visit www.incyte.com.

Forward Look Statements

Except for the historical information set forth herein, the matters set forth in this press release, including without limitation statements with respect to Incyte earning a second payment of \$60 million once Novartis achieves reimbursement and pricing approval in specific EU countries and the European Commission generally following the recommendations of the CHMP, contain predictions, estimates and other forward-looking statements.

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 ruxolitinib, the high degree of risk and uncertainty associated with the regulatory approval process, risks associated with Incyte's dependence on its relationships with its collaboration partners, and other risks detailed from time to time in Incyte's reports filed with the Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2011.

Incyte disclaims any intent or obligation to update these forward-looking statements.

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.
2. 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.



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