Jakavi® (ruxolitinib) First Medication to Receive European Commission Approval to Treat Patients with Myelofibrosis

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WILMINGTON, Del.--(BUSINESS WIRE)--Aug. 28, 2012-- Incyte Corporation (Nasdaq: INCY) today announced that its strategic collaborator, Novartis, received approval from the European Commission for Jakavi® (INC424, ruxolitinib), an oral JAK 1 and JAK 2 inhibitor discovered by Incyte, 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.

Incyte entered into a worldwide collaboration and license agreement with Novartis in 2009. Novartis received exclusive rights to the development and potential commercialization of ruxolitinib in all hematology-oncology indications outside of the United States. Incyte retained exclusive rights for the development and commercialization of ruxolitinib in the United States, and received approval from the U.S. Food and Drug Administration in November 2011 for ruxolitinib, marketed in the United States under the brand name Jakafi®. Jakafi® (ruxolitinib) is approved in the United States for the treatment of patients with intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis.

Important Safety Information for Jakafi in the United States

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 in the Full Prescribing Information]. 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, go to www.jakafi.com or www.incyte.com.

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.

Source: Incyte Corporation

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