



Incyte Earns \$25 Million Milestone as Jakavi® (ruxolitinib) Recommended for Approval in Europe for Polycythemia Vera

January 23, 2015

WILMINGTON, Del.--(BUSINESS WIRE)--Jan. 23, 2015-- Incyte Corporation (Nasdaq: INCY) today announced that it has earned a \$25 million milestone payment from Novartis. This payment was triggered by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopting a positive opinion for Jakavi® (ruxolitinib) for the treatment of adult patients with polycythemia vera (PV) who are resistant to or intolerant of hydroxyurea. Incyte expects to record this amount as contract revenue, and receive the \$25 million payment, in the first quarter of 2015.

"We are very pleased with the progress that Novartis has made in the global development and commercialization of Jakavi," stated Hervé Hoppenot, President and Chief Executive Officer of Incyte. "This recommendation for approval in Europe, the second indication for Jakavi and many months ahead of schedule, is further evidence that our innovative scientific advances can offer significant benefit to patients."

Under the Incyte-Novartis Collaboration and License Agreement signed in 2009, Novartis received exclusive development and commercialization rights to ruxolitinib outside of the United States for all hematologic and oncologic indications, and sells ruxolitinib under the name Jakavi. Ruxolitinib is marketed by Incyte in the United States as Jakafi® (ruxolitinib).

About Polycythemia Vera

Polycythemia vera (PV) is a myeloproliferative neoplasm (MPN) and is typically characterized by elevated hematocrit, the volume percentage of red blood cells in whole blood, which can lead to a thickening of the blood and an increased risk of blood clots, as well as an elevated white blood cell and platelet count¹. Patients with PV who fail to consistently maintain appropriate blood count levels, including appropriate hematocrit levels, have an approximately four times higher risk of major thrombosis (blood clots) or cardiovascular death². Patients with PV can also suffer from an enlarged spleen and a significant symptom burden which may be attributed to thickening of the blood and lack of oxygen to parts of the body³. These symptoms commonly include fatigue, itching, night sweats, bone pain, fever, and weight loss⁴.

Approximately 100,000 patients in the U.S. are living with PV⁵. Current standard treatment for PV is phlebotomy (the removal of blood from the body) plus aspirin. When phlebotomy can no longer control PV, chemotherapy such as hydroxyurea, or interferon, is utilized^{4,6}. Approximately one in four patients with PV are considered uncontrolled^{7,8} because they have an inadequate response to or are intolerant of hydroxyurea, the most commonly used chemotherapeutic agent for the treatment of PV.

About Incyte

Incyte Corporation is a Wilmington, Delaware-based biopharmaceutical company focused on the discovery, development and commercialization of proprietary therapeutics, primarily for oncology. For additional information on Incyte, please visit the Company's website at www.incyte.com.

About Jakafi® (ruxolitinib)

Jakafi is a first-in-class JAK1/JAK2 inhibitor approved by the U.S. Food and Drug Administration for treatment of people with polycythemia vera (PV) who have had an inadequate response to or are intolerant of hydroxyurea.

Jakafi is also indicated for treatment of people with intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF, and post-essential thrombocythemia MF.

Jakafi is marketed by Incyte in the United States and by Novartis as Jakavi® (ruxolitinib) outside the United States.

Important Safety Information

Jakafi can cause serious side effects, including:

Low blood counts: Jakafi may cause your platelet, red blood cell, or white blood cell counts to be lowered. If you develop bleeding, stop taking Jakafi and call your healthcare provider. Your healthcare provider will perform blood tests to check your blood counts before you start Jakafi and regularly during your treatment. Your healthcare provider may change your dose of Jakafi or stop your treatment based on the results of your blood tests. Tell your healthcare provider right away if you experience unusual bleeding, bruising, fatigue, shortness of breath, or a fever.

Infection: You may be at risk for developing a serious infection during treatment with Jakafi. Tell your healthcare provider if you develop any of the following symptoms of infection: chills, nausea, vomiting, aches, weakness, fever, painful skin rash or blisters.

Skin cancers: Some people who take Jakafi have developed certain types of non-melanoma skin cancers. Tell your healthcare provider if you develop any new or changing skin lesions.

The most common side effects of Jakafi include: anemia, low platelet count, bruising, dizziness, headache.

These are not all the possible side effects of Jakafi. Ask your pharmacist or healthcare provider for more information. Tell your healthcare provider about any side effect that bothers you or that does not go away.

Before taking Jakafi, tell your healthcare provider about all the medications, vitamins, and herbal supplements you are taking and all your medical

conditions, including if you have an infection, have or had tuberculosis (TB), or have been in close contact with someone who has TB, have or had liver or kidney problems, are on dialysis, had skin cancer or have any other medical condition. Take Jakafi exactly as your healthcare provider tells you. Do not change or stop taking Jakafi without first talking to your healthcare provider. Do not drink grapefruit juice while on Jakafi.

Women should not take Jakafi while pregnant or planning to become pregnant, or if breast-feeding.

Please see the Full Prescribing Information available at www.jakafi.com, which includes a more complete discussion of the risks associated with Jakafi.

References

- ¹Leukemia & Lymphoma Society. Polycythemia Vera Facts 2012. Available at: <https://www.lls.org/content/nationalcontent/resourcecenter/freeeducationmaterials/mpd/pdf/polycythemiavera.pdf>.
- ² Marchioli R, et al. N Engl J Med. 2013;368:22-33.
- ³National Institutes of Health <http://www.nhlbi.nih.gov/health/health-topics/topics/poly/signs>.
- ⁴ Passamonti F. Blood 2012;120(2):275-84
- ⁵ Data on file. Incyte Corporation
- ⁶ Vannucchi AM. Blood 2014;124(22):3212-20.
- ⁷ Barosi G, Birgegard G, Finazzi G, et al. Br J Haematol. 2010;149:961-3.
- ⁸ Alvarez-Larrán A, Pereira A, Cervantes F, et al. Blood. 2012;119:1363-9



Source: Incyte Corporation

Incyte Corporation
Michael Booth, DPhil
Vice President, Investor Relations
302-498-5914