

Incyte Announces Positive Top-Line Results from Phase III Study of Ruxolitinib in Patients with Polycythemia Vera

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- *Study of ruxolitinib versus best available therapy for patients with polycythemia vera who are resistant to or intolerant of hydroxyurea met primary endpoint*
- *Ruxolitinib is the first selective JAK1/JAK2 inhibitor to demonstrate efficacy in a Phase III trial for treating polycythemia vera*
- *Data expected to be presented at an upcoming scientific meeting*
- *Supplemental new drug application planned for submission to U.S. Food and Drug Administration this year*

WILMINGTON, Del.--(BUSINESS WIRE)--Mar. 7, 2014-- Incyte Corporation (Nasdaq: INCY) today announced that a pivotal Phase III trial of ruxolitinib compared to best available therapy in patients with polycythemia vera who are resistant to or intolerant of hydroxyurea has met its primary endpoint of achieving phlebotomy independence and reducing spleen size by 35 percent or more. The safety profile of ruxolitinib was generally consistent with previous studies based on initial review of the data. Ruxolitinib, marketed as Jakafi® (ruxolitinib) in the United States, is approved to treat people with intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF.

"One out of four patients with polycythemia vera remain uncontrolled despite existing standard therapies, and these patients face a profound symptom burden and are at greater risk of cardiovascular complications. These Phase III data give us confidence that ruxolitinib may offer a welcome new treatment option," stated Herve Hoppenot, President and Chief Executive Officer, Incyte.

The global, randomized, open-label Phase III trial, called RESPONSE, was conducted at 109 sites. The trial included 222 patients with polycythemia vera resistant to or intolerant of hydroxyurea. Patients were randomized 1:1 to receive either ruxolitinib (10 mg twice-daily) or best available therapy. The dose was adjusted as needed throughout the trial.

The primary endpoint of the trial is the proportion of patients whose hematocrit level is controlled in absence of phlebotomy and whose spleen volume is reduced by 35 percent or more from baseline as assessed by imaging at 32 weeks. In addition to safety, key secondary endpoints include durable response and complete hematological remission.

Data from RESPONSE are expected to be presented at an upcoming scientific meeting and submitted to the U.S. Food and Drug Administration this year.

About Polycythemia Vera

Polycythemia vera (PV) is a myeloproliferative neoplasm (MPN) characterized by an overproduction of normal red blood cells, white blood cells and platelets that leads to an increased risk of thrombosis.¹⁻⁴ Erythrocytosis (elevated red blood cell mass) is the most prominent clinical manifestation of PV, distinguishing it from other MPNs.⁵ PV may occur at any age but often presents later in life, with a median age at diagnosis of 60 years.^{6,7} Approximately 100,000 patients in the United States are living with PV.⁸ and approximately 25 percent of patients with PV develop resistance to or intolerance of hydroxyurea^{9,10} and are considered uncontrolled.

Although patients may be asymptomatic for many years, PV is associated with significant symptom burden, and the most common signs and symptoms of PV are fatigue, pruritus, night sweats, bone pain, fever and weight loss.¹¹ Splenomegaly is present in 30 percent to 40 percent of patients with PV.¹¹ In patients who experience severe and burdensome symptoms, data show that the disease causes a significant and clinically meaningful erosion of quality of life.^{12,13}

About Jakafi

Jakafi is a prescription medicine approved by the U.S. Food and Drug Administration to treat 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 while taking Jakafi. Tell your healthcare provider if you develop symptoms such as chills, nausea, vomiting, aches, weakness, fever, or painful skin rash or blisters.

The most common side effects of Jakafi include dizziness and headache.

These are not all the possible side effects of Jakafi. Ask your healthcare provider or pharmacist 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 liver or kidney problems, are on dialysis, or have any other medical condition. Do not drink grapefruit juice while taking 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.

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 website at www.incyte.com.

Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including without limitation, statements as to Incyte's confidence that ruxolitinib may offer a welcome new treatment option for patients with uncontrolled PV and the expectation that data from the RESPONSE trial will be presented at an upcoming scientific meeting and submitted to the U.S. Food and Drug Administration this year, contain predictions, estimates and other forward-looking statements.

These forward-looking statements are based on Incyte's current expectations and 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, risks related to market competition, the results of further research and development, risks that results of clinical trials may be unsuccessful or insufficient to meet applicable regulatory standards, other market or economic factors and technological advances, unanticipated delays, the ability of Incyte to compete against parties with greater financial or other resources, 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, 2013.

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

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