

Two Phase 3 Studies Reinforce Sustained Benefits of Treatment with Jakafi® (ruxolitinib) in Patients with Myeloproliferative Neoplasms (MPNs)

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COMFORT-II data demonstrate that patients with myelofibrosis treated with Jakafi achieved a 33 percent reduction in the risk of death after five years

WILMINGTON, Del.--(BUSINESS WIRE)--Dec. 5, 2015-- Incyte Corporation (Nasdaq:INCY) announces data from two Phase 3 studies evaluating the long-term safety and efficacy of Jakafi® (ruxolitinib) in patients with Myeloproliferative Neoplasms (MPNs). In myelofibrosis (MF), results of a five-year follow-up from the COMFORT-II study demonstrate a continued survival benefit in patients originally randomized to ruxolitinib compared with patients randomized to best available therapy (BAT), with a 33 percent reduction in the risk of death (HR, 0.67; 95%CI, 0.44-1.02; $P=.06$). Because patients in the BAT arm had crossed over to receive ruxolitinib therapy (median 17 months after randomization), these data may suggest that earlier treatment with ruxolitinib may be associated with improved long-term survival in patients with intermediate-2 or high-risk MF. Additionally, 53 percent of patients treated with ruxolitinib ($n=78/146$) achieved at least a 35 percent reduction in spleen volume from baseline that was sustained over time (median duration 3.2 years).

"These data from the COMFORT-II study reinforce the positive and long-term clinical benefits seen in patients with myelofibrosis who are treated with Jakafi," said Rich Levy, MD, Chief Drug Development Officer, Incyte. "The reduction in the risk of death and the sustained improvements in spleen volume are meaningful and important results for the community of patients with this rare blood cancer."

An analysis of the RESPONSE study is also planned for presentation at ASH. Previously published results in the *New England Journal of Medicine* showed that treatment with ruxolitinib, compared to standard therapy improved hematocrit control and reduced spleen volume in patients with polycythemia vera (PV) who had an inadequate response to or had unacceptable side effects from hydroxyurea (HU). The data at ASH demonstrate that in patients with elevated white blood cell (WBC) counts at baseline, a greater proportion of patients in the ruxolitinib treatment arm (45%) achieved normalization of their WBC counts (achieving a $WBC \leq 10 \times 10^9/L$ or a $\geq 50\%$ reduction from baseline) compared to BAT (22%) or HU (9%) at week 32.

These data are scheduled for presentation at the 57th American Society of Hematology Annual Meeting taking place December 5-8, 2015 in Orlando, FL.

Results from the COMFORT-II Study

Data from a five-year follow-up of the COMFORT-II trial, a randomized, open-label Phase 3 study evaluating long-term safety and efficacy of ruxolitinib in patients with intermediate-2 or high-risk primary myelofibrosis, post-PV myelofibrosis, or post-ET myelofibrosis, allowing crossover from the BAT arm to ruxolitinib after 48 weeks upon protocol-defined progression, revealed that 53 percent of patients treated with ruxolitinib ($n=78/146$) achieved at least a 35 percent reduction in spleen volume from baseline while on treatment during the study. Additionally, approximately one-third of evaluable JAK2 V617F-positive patients had more than a 20 percent reduction in allele burden at 3.2 years (38%) and 3.7 years (31%). Patients treated with ruxolitinib also experienced improvements in bone marrow fibrosis (15.8%) with 32.2 percent reporting stable fibrosis scores.

Overall, 59 (40%) and 35 (48%) deaths were reported in the ruxolitinib and BAT arms, respectively. Median overall survival (OS) was not reached in the ruxolitinib arm and was 4.1 years in the group of patients originally receiving BAT. There was a 33 percent reduction in risk of death with ruxolitinib (HR, 0.67; 95 percent CI, 0.44-1.02; $P=.06$). The estimated probability of survival at 5 years was 56 percent with ruxolitinib and 44 percent with patients originally receiving BAT. At week 48, BAT patients were allowed to cross over to receive ruxolitinib upon protocol-defined progression and after week 48 all BAT patients, irrespective of their progression status, were allowed to crossover to receive ruxolitinib; therefore, a confounding effect on OS was observed. An analysis correcting for crossover will be presented.

Adverse events (AEs) were consistent with those reported in previous studies of ruxolitinib and there was no increase in the incidence of AEs with longer exposure to treatment.

COMFORT-II is scheduled for presentation as an oral session by Dr. Claire Harrison, Guy's and St. Thomas' NHS Foundation Trust, Guy's Hospital, Saturday, December 5, 2015, 9:30-11:30 AM EST, Room W224.

Results from the RESPONSE Study

The RESPONSE trial is a Phase 3 open-label study evaluating long-term safety and efficacy of ruxolitinib in patients with PV compared to BAT who had an inadequate response to or had unacceptable side effects from HU. The analysis from RESPONSE to be presented at ASH shows that patients who received ruxolitinib had greater mean reductions in WBC counts compared with BAT or the HU subgroup of the BAT arm, and these reductions were maintained over time. In patients with baseline WBC counts $\geq 11 \times 10^9/L$, worsening WBC counts were observed in 10.8 percent of patients in the ruxolitinib arm versus 35.4 percent in the BAT arm ($P=0.0002$) and 47.8 percent in the HU subgroup ($P<0.0001$). In this same subgroup of patients with elevated WBC counts at baseline, a greater proportion of patients in the ruxolitinib arm (45%) normalized their WBC counts (achieving a $WBC \leq 10 \times 10^9/L$ or a $\geq 50\%$ reduction from baseline) compared with BAT (22%) or HU (9%) at week 32. The median time to achieve this response with ruxolitinib therapy was 8 weeks.

These data are scheduled for presentation as a poster session by Dr. Carole Miller, Saint Agnes Cancer Institute, Monday, December 7, 2015, 6:00-8:00 PM EST, Hall A.

About Myelofibrosis

MF is part of a group of related rare blood cancers known as myeloproliferative neoplasms (MPNs) where a patient's bone marrow can no longer

produce enough normal blood cells, causing the spleen to enlarge¹. As a result, patients with MF may suffer from debilitating symptoms and have a poor quality of life². After diagnosis, patients with MF have a decreased life expectancy, with an average survival of approximately five to six years³. Although allogeneic stem cell transplantation may cure MF, the procedure is associated with significant morbidity and transplant-related mortality, and is available to less than 5% of patients who are young and fit enough to undergo the procedure⁴.

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 count⁵. 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 death⁶. 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 body⁷. These symptoms commonly include fatigue, itching, night sweats, bone pain, fever, and weight loss⁸.

Approximately 100,000 patients in the U.S. are living with PV⁹. 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^{10,11}. Approximately one in four patients with PV are considered uncontrolled^{12,13} because they have an inadequate response to or are intolerant of hydroxyurea, the most commonly used chemotherapeutic agent for the treatment of PV.

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.

Full Prescribing Information, including a more complete discussion of the risks associated with Jakafi, is available at www.jakafi.com.

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.

Forward Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including statements regarding the long-term efficacy and safety of Jakafi, contain predictions, estimates and other forward-looking statements. These forward-looking statements are based on the Company's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments and the risks related to the efficacy or safety of the Company's development pipeline, the results of further research and development, the high degree of risk and uncertainty associated with drug development, clinical trials and regulatory approval processes, other market or economic factors and competitive and technological advances; and other risks detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, including its Form 10-Q for the quarter ended September 30, 2015. Incyte disclaims any intent or obligation to update these forward-looking statements.

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