



Jakafi® (ruxolitinib) Product Label Expanded to Include Overall Survival Data and Additional Safety and Dosing Information

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Jakafi is the first and only FDA-approved treatment for patients with intermediate or high-risk myelofibrosis

WILMINGTON, Del.--(BUSINESS WIRE)--Jul. 28, 2014-- Incyte Corporation (Nasdaq:INCY) announced today that the U.S. Food & Drug Administration (FDA) has approved supplemental labeling for Jakafi® (ruxolitinib) to include new Kaplan-Meier overall survival curves as well as additional safety and dosing information. The new overall survival information is based on three-year data from the two pivotal Phase III trials, COMFORT-I and II, and shows that at three years the probability of survival for patients treated with Jakafi in COMFORT-I was 70% and for those patients originally randomized to placebo it was 61%. In COMFORT-II, at three years the probability of survival for patients treated with Jakafi was 79% and for patients originally randomized to best available therapy (BAT) it was 59%.

Both Phase III trials allowed for crossover from the control arm to Jakafi, and the median time to crossover in COMFORT-I and COMFORT-II was 9 months and 17 months, respectively. All patients who crossed over to Jakafi continued to be grouped within their original randomized assignment for these overall survival analyses.

"Inclusion of the overall survival data from COMFORT-I and II in the Jakafi product label is important to healthcare professionals and patients, and adds to the growing body of knowledge regarding treatment with Jakafi," stated Hervé Hoppenot, President and Chief Executive Officer of Incyte.

The new product label also includes additional guidance on safety and dosing including information regarding the risk and management of tuberculosis, modified information regarding symptom exacerbation following interruption and discontinuation of Jakafi, and modified dosing guidelines regarding concomitant use with CYP3A4 inhibitors and fluconazole.

The full prescribing information for Jakafi can be found at www.incyte.com.

About COMFORT-I and COMFORT-II (Controlled MyeloFibrosis Study with ORal JAK Inhibitor Treatment)

COMFORT-I was a randomized (1:1), double-blind, placebo-controlled Phase III study comparing the efficacy and safety of ruxolitinib to placebo in 309 patients with primary myelofibrosis (PMF), post-polycythemia vera myelofibrosis (PPV-MF) or post-essential thrombocythemia myelofibrosis (PET-MF) and involved 89 clinical sites in the US, Canada and Australia. The primary endpoint was the proportion of patients achieving a reduction in spleen volume of 35% or more from baseline to week 24 as measured by MRI (or CT scan in applicable patients). Key secondary endpoints included duration of maintenance of a 35% or greater reduction in spleen volume from baseline, the proportion of patients with 50% or more reduction in symptom improvement as measured by the modified Myelofibrosis Symptom Assessment Form (MFSAF) version 2.0 electronic diary and overall survival at 3 years.

COMFORT-II was a randomized (2:1), open-label Phase III study of ruxolitinib versus best available therapy (BAT; administered at doses and schedules determined by the investigator, and included the option of no treatment) that enrolled 219 patients with primary MF, PPV-MF or PET-MF in 56 study locations in Europe. The primary endpoint was the proportion of patients achieving a reduction in spleen volume of 35% or greater from baseline to week 48 as measured by MRI (or CT scan in applicable patients). Secondary endpoints included spleen size reduction at 24 weeks, duration of spleen size reduction, change in bone marrow histomorphology, leukemia-free survival, progression-free survival and overall survival at 3 years.

In both COMFORT-I and II, patients randomized to placebo and best available therapy were allowed to cross-over to receive Jakafi at week 24 and week 48, respectively. Patients randomized to placebo or best available therapy could also cross over to Jakafi prior to week 24 or 48 based on progression-driven events or at the physician's discretion. All patients who crossed over to Jakafi continued to be grouped within their original randomized assignment for these overall survival analyses.

About Jakafi® (ruxolitinib)

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. 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.incyte.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, primarily for oncology. For additional information on Incyte, please visit the company's website at www.incyte.com.



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