Jakafi™ (ruxolitinib) Fact Sheet

Jakafi™ is the first and only FDA-approved treatment for myelofibrosis (MF), a potentially life-threatening blood cancer characterized by bone marrow failure, enlarged spleen and debilitating symptoms.¹ Jakafi, discovered and developed by Incyte, is the first in a new class of drugs, known as JAK inhibitors, to be FDA-approved for the treatment of MF or any other indication.

An oral prescription therapy taken twice daily, Jakafi is indicated for the treatment of patients with intermediate or high-risk MF, including primary MF, post–polycythemia vera MF (PPV-MF) and post–essential thrombocythemia MF (PET-MF). Intermediate and high-risk patients represent 80% to 90% of all MF patients and anyone over the age of 65 or who have or have had any of the following: anemia, constitutional symptoms, elevated white blood cell or blast counts or platelet counts less than 100 X 10⁹/L.²³

The recommended starting dose for most patients is either 15 mg or 20 mg given orally twice daily based on the patient’s platelet count. Dosing should be adjusted based on safety and efficacy.

While the exact cause of MF is unknown, researchers believe that the condition results from dysregulation of a cell signaling pathway called the JAK (Janus kinase) pathway.⁴ Dysregulation of this pathway may be caused by a number of genetic mutations, such as the JAK2V617F, MPL and LNK mutations.⁵ The resulting abnormal JAK activity has been linked to the enlarged spleens and other debilitating symptoms seen in most patients with MF.

Under the terms of the 2009 Incyte and Novartis worldwide collaboration and license agreement, Incyte retained exclusive rights for the development and commercialization of Jakafi in the US. Novartis received exclusive rights to the development and potential commercialization of ruxolitinib (INC424) in all hematology-oncology indications outside of the US.

Clinical Trial Data⁶
Approval of Jakafi was based on two phase III clinical trials, COMFORT-I and COMFORT-II (COntrolled MyeloFibrosis Study with ORal JAK Inhibitor Therapy).

COMFORT-I
• Phase III, randomized, double-blind study comparing Jakafi to placebo
• The study included 309 patients with primary MF, PPV-MF or PET-MF in 89 study locations in the United States, Canada and Australia
• The primary endpoint was reduction in spleen volume of 35% or more at week 24
• The trial met the primary endpoint, showing that 41.9% of patients treated with Jakafi experienced a 35% or greater reduction in spleen volume at 24 weeks, compared with 0.7% of patients in the placebo arm (P<0.0001)
• Most patients treated with Jakafi had some reduction in spleen volume
• In addition, the study showed statistically significant improvements of MF-related symptoms, a key secondary efficacy endpoint
COMFORT-II

- Phase III, randomized, open-label study comparing Jakafi to best available therapy (BAT), including therapies such as hydroxyurea and glucocorticoids
- The study included 219 patients with primary MF, PPV-MF or PET-MF in 56 study locations in Europe
- The primary endpoint was reduction in spleen volume of 35% or more at week 48
- The study demonstrated a reduction in spleen volume of 35% or greater in 28.5% of patients treated with Jakafi compared with 0% of patients in the BAT arm at 48 weeks (P<0.0001)

The most common adverse reactions in both studies were thrombocytopenia and anemia. These events were manageable and rarely led to discontinuation of Jakafi treatment. The most common non-hematologic adverse reactions were bruising, dizziness and headache.

IncyteCARES

Incyte has created IncyteCARES (Connecting to Access, Reimbursement, Education and Support), a comprehensive program that connects patients to ongoing support and resources during treatment with Jakafi. The program offers access to trained nurse professionals and financial support, as well as to ongoing education, tools and resources.

Incyte is committed to providing access and financial assistance to patients with myelofibrosis who cannot afford this medicine. Incyte will provide Jakafi free of charge to eligible patients who do not have insurance and will also offer co-pay assistance to eligible individuals with commercial insurance. More information about IncyteCARES is available by calling 1-855-4-Jakafi (855-452-5234).

Important Safety Information

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 <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]. 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.


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References


6 Data on File. Incyte Corporation.