Incyte Provides Regulatory Update on Ruxolitinib Extended-Release Tablets

March 24, 2023

WILMINGTON, Del.--(BUSINESS WIRE)--Mar. 23, 2023-- Incyte (Nasdaq:INCY) today announced that the U.S. Food and Drug Administration (FDA) has issued a complete response letter for ruxolitinib extended-release (XR) tablets, a JAK1/JAK2 inhibitor, for once-daily (QD) use in the treatment of certain types of myelofibrosis (MF), polycythemia vera (PV) and graft-versus-host disease (GVHD).

The complete response letter states that the FDA cannot approve the application in its present form. The FDA acknowledged that the study submitted in the New Drug Application (NDA) met its objective of bioequivalence based on area under the curve (AUC) parameters but identified additional requirements for approval. Incyte intends to meet with the FDA to determine appropriate next steps.

“While we are disappointed that the FDA issued a complete response letter for ruxolitinib extended-release tablets, we remain committed to advancing care for people with myeloproliferative neoplasms and GVHD,” said Hervé Hoppenot, Chief Executive Officer, Incyte. “We will work closely with the FDA on the appropriate next steps to address their comments.”

The NDA was based on two studies designed to show that ruxolitinib XR tablets are dosage strength proportional and bioequivalent to Jakafi® (ruxolitinib) tablets. The first study was designed to determine the relative bioavailability of ruxolitinib XR tablets to Jakafi tablets and to demonstrate that ruxolitinib XR tablets are dosage strength proportional to Jakafi tablets. The second study was an open-label, randomized, two-period, two-way crossover study in 63 healthy adults evaluating the bioequivalence of the highest strength of ruxolitinib XR tablets (50 mg) dosed once-daily (QD) to the highest strength of Jakafi tablets (25 mg) dosed twice-daily (BID), following a single dose and at steady-state. Study results demonstrated that ruxolitinib XR 50 mg tablets dosed QD is bioequivalent to Jakafi 25 mg tablets dosed BID, based on AUC parameters.

About Jakafi® (ruxolitinib)

Jakafi® (ruxolitinib) is a JAK1/JAK2 inhibitor approved by the U.S. FDA for treatment of polycythemia vera (PV) in adults who have had an inadequate response to or are intolerant of hydroxyurea; intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF in adults; steroid-refractory acute GVHD in adult and pediatric patients 12 years and older; and chronic GVHD after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older[1].

Jakafi is a registered trademark of Incyte.

Important Safety Information

Jakafi can cause serious side effects, including:

Low blood counts: Jakafi® (ruxolitinib) may cause low platelet, red blood cell, and white blood cell counts. If you develop bleeding, stop taking Jakafi and call your healthcare provider. Your healthcare provider will do a blood test 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 develop or have worsening symptoms such as unusual bleeding, bruising, tiredness, 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.

Cancer: Some people have had certain types of non-melanoma skin cancers during treatment with Jakafi. Your healthcare provider will regularly check your skin during your treatment with Jakafi. Tell your healthcare provider if you develop any new or changing skin lesions during treatment with Jakafi.

Increases in cholesterol: You may have changes in your blood cholesterol levels during treatment with Jakafi. Your healthcare provider will do blood tests to check your cholesterol levels about every 8 to 12 weeks after you start taking Jakafi, and as needed.

Increased risk of major cardiovascular events such as heart attack, stroke or death in people who have cardiovascular risk factors and who are current or past smokers while using another JAK inhibitor to treat rheumatoid arthritis: Get emergency help right away if you have any symptoms of a heart attack or stroke while taking Jakafi, including: discomfort in the center of your chest that lasts for more than a few minutes, or that goes away and comes back, severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw, pain or discomfort in your arms, back, neck, jaw, or stomach, shortness of breath with or without chest discomfort, breaking out in a cold sweat, nausea or vomiting, feeling lightheaded, weakness in one part or on one side of your body, slurred speech

Increased risk of blood clots: Blood clots in the veins of your legs (deep vein thrombosis, DVT) or lungs (pulmonary embolism, PE) have happened in people taking another JAK inhibitor for rheumatoid arthritis and may be life-threatening. Tell your healthcare provider right away if you have any signs and symptoms of blood clots during treatment with Jakafi, including: swelling, pain, or tenderness in one or both legs, sudden, unexplained chest or upper back pain, shortness of breath or difficulty breathing

Possible increased risk of new (secondary) cancers: People who take another JAK inhibitor for rheumatoid arthritis have an increased risk of new (secondary) cancers, including lymphoma and other cancers. People who smoke or who smoked in the past have an added risk of new cancers.

The most common side effects of Jakafi include: for certain types of myelofibrosis (MF) and polycythemia vera (PV) – low platelet or red blood cell counts, bruising, dizziness, headache, and diarrhea; for acute GVHD – low platelet counts, low red or white blood cell counts, infections, and swelling; and for chronic GVHD – low red blood cell or platelet counts and infections including viral infections.

These are not all the possible side effects of Jakafi. Ask your pharmacist or healthcare provider for more information. Call your doctor for medical advice about side effects.

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 low white or red blood cell counts, have or had tuberculosis (TB) or have been in close contact with someone who has TB, had shingles (herpes zoster), have or had hepatitis B, have or had liver or kidney problems, are on dialysis, have high cholesterol or triglycerides, had cancer, are a current or past smoker, had a blood clot, heart attack, other heart problems or stroke, or have any other medical condition. Take Jakafi exactly as your healthcare provider tells you. Do not change your dose or stop taking Jakafi without first talking to your healthcare provider.

Women should not take Jakafi while pregnant or planning to become pregnant. Do not breastfeed during treatment with Jakafi and for 2 weeks after the final dose.

Please see the Full Prescribing Information, which includes a more complete discussion of the risks associated with Jakafi.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call **1-800-FDA-1088**.

You may also report side effects to Incyte Medical Information at 1-855-463-3463.

About Incyte
Incyte is a Wilmington, Delaware-based, global biopharmaceutical company focused on finding solutions for serious unmet medical needs through the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit Incyte.com and follow @Incyte.

Forward-Looking Statements
Except for the historical information set forth herein, the matters set forth in this press release, including statements regarding whether and when ruxolitinib XR might provide a successful treatment option for patients with myelofibrosis, polycythemia vera and graft-versus-host disease, 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: unanticipated delays; further research and development and the results of clinical trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials; the effects of the COVID-19 pandemic and measures to address the pandemic on Incyte and its partners' clinical trials, supply chain, other third-party providers and development and discovery operations; determinations made by the U.S. FDA and other regulatory authorities outside of the United States; the efficacy or safety of Incyte and its partners' products; the acceptance of Incyte and its partners' products in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; and other risks detailed from time to time in Incyte's reports filed with the Securities and Exchange Commission, including its annual report for the year ending December 31, 2022. Incyte disclaims any intent or obligation to update these forward-looking statements.

[1] Jakafi (ruxolitinib) tablets: Prescribing Information. U.S. Food and Drug Administration.

View source version on businesswire.com: https://www.businesswire.com/news/home/20230323005785/en/

Media
Jenifer Antonacci
+1 302 498 7036
jantonacci@incyte.com

Kristen Griffiths
+1 302 498 7012
kgriffiths@incyte.com

Investors
Christine Chiou
+1 302 274 4773
cchiou@incyte.com

Source: Incyte