



9/22/2021

Incyte Announces FDA Approval of Jakafi® (ruxolitinib) for Treatment of Chronic Graft-Versus-Host Disease (GVHD)

- Jakafi is approved for treatment of chronic GVHD after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older
- Today's approval marks the fourth FDA-approved indication for Jakafi, which received FDA-approval in 2019 for steroid-refractory acute GVHD in adult and pediatric patients 12 years and older

WILMINGTON, Del.--(BUSINESS WIRE)-- Incyte (Nasdaq:INCY) today announced that the U.S. Food and Drug Administration (FDA) has approved Jakafi® (ruxolitinib) for treatment of chronic graft-versus-host disease (GVHD) after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older.

"GVHD is the leading cause of morbidity and mortality in patients following an allogeneic stem cell transplant, yet there historically have been limited treatment options available beyond first-line systemic therapies," stated Steven Stein, M.D., Chief Medical Officer, Incyte. "Incyte is proud to have contributed to the overall scientific understanding of GVHD through our REACH program, which has led to important treatment advances on behalf of patients and the medical community, including today's approval of Jakafi for certain people who develop chronic GVHD."

The FDA approval was based on the REACH3 study, a Phase 3, randomized, open-label, multicenter study of Jakafi in comparison to best available therapy (BAT) for treatment of steroid-refractory chronic GVHD after allogeneic stem cell transplantation. The primary endpoint of overall response rate (ORR) at Week 24 (i.e., Cycle 7 Day 1) was 49.7% for Jakafi compared to 25.6% for BAT ($P < 0.0001$)¹. Furthermore, the ORR through Cycle 7 Day 1 was 70% for Jakafi compared to 57% for BAT². The most common hematologic adverse reactions (incidence > 35%) were anemia and thrombocytopenia. The most common nonhematologic adverse reactions (incidence \geq 20%) were infections (pathogen not specified) and viral infection. Full results from the REACH3 study **were published** in the New England Journal of Medicine (NEJM).

“Nearly half of the people who develop chronic GVHD do not respond adequately to steroids – the current standard of care – making this life-threatening condition particularly challenging to treat,” said Dr. Robert Zeiser, University Medical Center Freiburg, Department of Hematology, Oncology and Stem Cell Transplantation, Freiburg, Germany, the principal investigator of the REACH3 trial. “In this clinical trial, treatment with Jakafi demonstrated significantly improved outcomes across a range of efficacy measures compared to best available therapy. This approval represents a significant advancement in the treatment of appropriate patients with chronic GVHD – for both the patients who face a poor prognosis and the healthcare providers who struggle to effectively treat them.”

GVHD is a condition that can occur after an allogeneic stem cell transplant (the transfer of stem cells from a donor) in which the donated cells initiate an immune response and attack the transplant recipient’s organs. There are two major forms of GVHD: acute, which generally occurs within 100 days of transplant, and chronic, which generally occurs more than 100 days after transplant³. Both forms are associated with significant morbidity and mortality and can affect multiple organ systems.

“In the U.S., there are over 14,000 people living with chronic GVHD, many of whom face significant complications that may impair daily activities and linger for years,” said Susan Stewart, Executive Director, BMT InfoNet. “The approval of Jakafi is an exciting development for the GVHD community and an important step forward in the treatment of a disease with few options.”

Jakafi’s supplemental New Drug Application (sNDA) in chronic GVHD was reviewed under the FDA’s Priority Review program as well as the Project Orbis program, an initiative of the FDA Oncology Center of Excellence that provides a framework for concurrent submission and review of oncology drugs among its international partners. Participating countries for this application include Canada, Australia, Switzerland, Brazil and the United Kingdom.

Incyte is committed to supporting patients and removing barriers to access medicines. Eligible patients in the U.S. who are prescribed Jakafi have access to IncyteCARES (Connecting to Access, Reimbursement, Education and Support), a comprehensive program offering patient support, including financial assistance and ongoing education and resources to eligible patients. More information about IncyteCARES is available by visiting www.incytecares.com or calling 1-855-452-5234.

About REACH3

REACH3 (NCT03112603), a randomized, open-label, multicenter Phase 3 study co-sponsored by Novartis and Incyte, evaluated the safety and efficacy of ruxolitinib compared with best available therapy (BAT) in patients with steroid-refractory chronic GVHD.

For more information about the study, please visit <https://clinicaltrials.gov/ct2/show/NCT03112603>.

About Jakafi® (ruxolitinib)

Jakafi is a JAK1/JAK2 inhibitor approved by the U.S. FDA for treatment of chronic GVHD after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older.

Jakafi is also indicated 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, and for treatment of steroid-refractory acute GVHD in adult and pediatric patients 12 years and older².

Jakafi is marketed by Incyte in the U.S. and by Novartis as Jakavi® (ruxolitinib) outside the U.S. Jakafi is a registered trademark of Incyte. Jakavi is a registered trademark of Novartis AG in countries outside the U.S.

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 MF and 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](https://twitter.com/Incyte).

Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including statements regarding whether or when Jakafi might provide a successful treatment option for patients with steroid-refractory chronic GVHD, the Company's ongoing clinical development program for ruxolitinib and the REACH clinical trial program, 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 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 and the ability to enroll subjects in accordance with planned schedules; the effects of the COVID-19 pandemic and measures to address the pandemic on the Company's clinical trials supply chain and other third-party providers and development and discovery operations; determinations made by the FDA or other regulatory authorities; the Company's dependence on its relationships with its collaboration partners; the efficacy or safety of the Company's products and the products of the Company's collaboration partners; the acceptance of the Company's products and the products of the Company's collaboration partners in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; and other risks detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, including its annual report and its quarterly report on Form 10-Q for the quarter ended June 30, 2021. The Company disclaims any intent or obligation to update these forward-looking statements.

1 Zeiser R, M.D., et al. Ruxolitinib for Glucocorticoid-Refractory Chronic Graft-versus-Host Disease. New England Journal of Medicine; July 2021.

2 Jakafi (ruxolitinib) tablets: Prescribing Information. U.S. Food and Drug Administration; September 2021.

3 Ferrara JL., et al. Graft-versus-host disease. Lancet. 2009;373(9674):1550-1561.

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Source: Incyte