Incyte Announces FDA Approval of Jakafi XR™ (ruxolitinib) Extended-Release Tablets for the Treatment of Myelofibrosis, Polycythemia Vera and Graft-Versus-Host Disease

May 1, 2026

- *Jakafi XR is a once-daily, film-coated, extended-release formulation of Jakafi®(ruxolitinib)*
- *Once-daily Jakafi XR was shown to provide consistent, day-long exposure comparable to twice-daily Jakafi*
- *Jakafi XR will be available for pharmacy orders by May 8*

WILMINGTON, Del.--(BUSINESS WIRE)--May 1, 2026-- Incyte (Nasdaq:INCY) today announced that the U.S. Food and Drug Administration (FDA) has approved Jakafi XR™ (ruxolitinib) extended-release tablets for the treatment of adults with intermediate- or high-risk myelofibrosis (MF); adults with polycythemia vera (PV) who have had an inadequate response to or are intolerant of hydroxyurea; as well as adults and children aged 12 years and older with steroid-refractory acute graft-versus-host disease (GVHD) or chronic GVHD after failure of one or two lines of systemic therapy.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20260501334677/en/

"The approval of Jakafi XR reinforces Incyte's leadership in hematology and our focus on meeting the evolving needs of patients with myeloproliferative neoplasms (MPNs) and GVHD," said Bill Meury, Chief Executive Officer, Incyte. "Jakafi XR offers appropriate patients and physicians a once-daily option, expanding choice without changing the well-established role of Jakafi in clinical practice."

FDA approval was based on a clinical study which demonstrated that a single 55 mg Jakafi XR tablet taken once-daily (QD) is bioequivalent to a single 25 mg Jakafi tablet, the immediate-release (IR) dosage form, taken twice-daily (BID). This means that, based on key measures of steady-state drug exposure, it delivers the same active ingredient at comparable levels throughout the day, indicating the potential for similar clinical benefit.[1]

The safety of Jakafi XR has been established from adequate and well-controlled studies of Jakafi in adult patients with myelofibrosis, polycythemia vera, and adult and pediatric patients with acute and chronic graft-versus-host-disease. The most common adverse reactions associated with Jakafi in these studies include:

- For certain patients with MF and PV: low platelet or red blood cell counts, bruising, dizziness, headache and diarrhea;
- For patients with acute GVHD: low platelet counts, low red or white blood cell counts, infections and swelling;
- And for patients with chronic GVHD: low red blood cell or platelet counts and infections, including viral infections.[2]

"Patients living with chronic conditions like MPNs and GVHD often struggle with managing complex treatment regimens or have multiple conditions," said Naveen Pemmaraju, M.D., Professor of Leukemia, Division of Cancer Medicine at The University of Texas MD Anderson Cancer Center. "Since its initial approval in 2011, ruxolitinib has helped transform the treatment landscape for patients with MPNs and GVHD. With the approval of Jakafi XR, appropriate patients now have the choice of a single daily tablet." Researchers at UT MD Anderson have led several clinical trials in the development of ruxolitinib.

Incyte is committed to supporting patients and removing barriers to access medicines. Eligible patients in the U.S. who are prescribed Jakafi XR have access to IncyteCARES (Connecting to Access, Reimbursement, Education and Support), a comprehensive program offering personalized patient support, including financial assistance and ongoing education and additional resources. More information about IncyteCARES is available by visiting www.incytecares.com or calling 1-855-452-5234, Monday through Friday, from 8 a.m. to 8 p.m. ET.

About Myelofibrosis

Myelofibrosis (MF) is a part of a group of rare, chronic blood cancers called myeloproliferative neoplasms, or MPNs. MF occurs when a bone marrow defect results in an abnormal production of blood cells, causing scar tissue to form, which can lead to severe anemia, weakness, fatigue and an enlarged spleen and liver. MF can result from a progression of other bone marrow diseases, including polycythemia vera and essential thrombocythemia, or it can occur on its own.[3]

About Polycythemia Vera

Polycythemia Vera (PV) is a part of a group of rare, chronic blood cancers called myeloproliferative neoplasms, or MPNs.[3] PV occurs when bone marrow produces too many red blood cells, white blood cells and often platelets. Increased red blood cells and platelets can cause the blood to thicken, leading to an increased risk of blood clotting complications, including deep vein thrombosis, stroke or heart attack.[4]

About Graft-Versus-Host Disease

Graft-versus-host disease (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, leading to significant morbidity and mortality. There are two major forms of GVHD: acute, which generally occurs within 100 days of transplant, and chronic, which generally occurs after 100 days of transplant. Both forms can affect multiple organ systems, including the skin, gastrointestinal (digestive) tract and liver.[5]

About Jakafi XR™ (ruxolitinib) Extended-Release Tablets

Jakafi XR™ (ruxolitinib) extended-release tablets are a once-daily (QD) formulation of ruxolitinib, a first-in-class JAK1/JAK2 inhibitor, approved by the U.S. FDA for the treatment of intermediate- or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis, and

post-essential thrombocythemia myelofibrosis in adults; polycythemia vera in adults who have had an inadequate response to or are intolerant of hydroxyurea; steroid-refractory acute graft-versus-host disease in adult and pediatric patients 12 years and older; and chronic graft-versus-host disease after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older.

It is not known if Jakafi XR is safe or effective in children for treatment of myelofibrosis or polycythemia vera.

Jakafi XR and the Jakafi XR logo are trademarks of Incyte.

About Jakafi® (ruxolitinib)

Jakafi® (ruxolitinib) is a JAK1/JAK2 inhibitor approved by the U.S. FDA for the 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.

It is not known if Jakafi is safe or effective in children for treatment of myelofibrosis or polycythemia vera.

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

IMPORTANT SAFETY INFORMATION

JAKAFI or JAKAFI XR can cause serious side effects, including:

Low blood counts: JAKAFI or JAKAFI XR may cause low platelet, red blood cell, and white blood cell counts. If you develop bleeding, stop taking JAKAFI or JAKAFI XR and call your healthcare provider. Your healthcare provider will do a blood test to check your blood counts before you start and regularly during your treatment. Your healthcare provider may change your dose 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
- a fever

Infection: You may be at risk for developing a serious infection during treatment with JAKAFI or JAKAFI XR. 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

Worsening of symptoms after interrupting or stopping treatment. Signs and symptoms of myelofibrosis may worsen after you stop treatment.

Do not interrupt or stop treatment without talking to your healthcare provider. Tell your healthcare provider right away if you have any of the following after stopping treatment:

- fever
- trouble breathing
- weakness
- night sweats
- feeling dizzy or lightheaded
- pain in left upper stomach area or left shoulder

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

Increases in cholesterol: You may have changes in your blood cholesterol levels during treatment with JAKAFI or JAKAFI XR. Your healthcare provider will do blood tests to check your cholesterol levels about every 8 to 12 weeks after you start taking JAKAFI or JAKAFI XR 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 get any symptoms of a heart attack or stroke during treatment with JAKAFI or JAKAFI XR, 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 or JAKAFI XR, 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 or JAKAFI XR include:

- for certain types of polycythemia vera (PV) – low platelet or red blood cell counts, bruising, dizziness, headache, and diarrhea
- for certain types of myelofibrosis (MF) – 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
- for chronic GVHD – low red blood cell or platelet counts and infections, including viral infections

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

Before taking JAKAFI or JAKAFI XR, tell your healthcare provider about:

- all the medications, vitamins, and herbal supplements you are taking
- your medical conditions, including if you
    - have or had low white or red blood cell counts
    - have an infection
    - 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 a high level of fat in your blood (high blood cholesterol or triglycerides)
    - have or have had a blood clot, heart attack, other heart problems, or stroke
    - are a current or past smoker
    - had cancer
    - have or had liver or kidney problems or are on dialysis. If you are on dialysis, JAKAFI or JAKAFI XR should be taken after your dialysis
    - have any other medical condition

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

How should I take JAKAFI or JAKAFI XR?

- Take exactly as your healthcare provider tells you.
- Do not change your dose or stop taking JAKAFI or JAKAFI XR without first talking to your healthcare provider. If you stop treatment, symptoms of your condition may return.
- If you miss a dose, take your next dose at your regular time. Do NOT take 2 doses at the same time.
- You may have regular blood tests during your treatment. Based on the results, your healthcare provider may change your dose or stop JAKAFI or JAKAFI XR.

- IF YOU ARE PRESCRIBED JAKAFI:
    - Take JAKAFI 2 times a day or exactly as your healthcare provider tells you, with or without food.
    - JAKAFI may also be given through certain nasogastric tubes.
    - Tell your healthcare provider if you cannot take JAKAFI by mouth. Your healthcare provider will decide if you can take JAKAFI through a nasogastric tube. Ask your healthcare provider to give you specific instructions on how to

properly take JAKAFI through a nasogastric tube.

- IF YOU ARE PRESCRIBED JAKAFI XR:
  - Take JAKAFI XR 1 time a day with or without food.
  - Swallow JAKAFI XR whole. Do not split, crush, or chew.

Please see the Full Prescribing Information, including Patient Information, which includes a more complete discussion of the risks associated with JAKAFI or JAKAFI XR at Jakafi.com.

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 redefining what's possible in biopharmaceutical innovation. Through deep scientific expertise and a relentless focus on patients, we have built an established portfolio of first-in-class medicines and an extensive portfolio of next-generation medicines across our key franchises: Hematology, Oncology and Inflammation and Autoimmunity.

To learn more, visit Incyte.com and Investor.Incyte.com. Follow us on social media: LinkedIn, X and Instagram.

Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this release, including statements regarding when Jakafi XR will be available in pharmacies; Incyte's leadership in hematology and its commitment to supporting the MPN and GVHD communities, Incyte's focus on advancing innovative treatments that help address the needs of patients, the potential for Jakafi XR to provide a successful treatment option for patients and offer patients and their providers choice and flexibility and Incyte's intent to work closely with payers and providers to help ensure access to Jakafi XR, contain predictions, estimates, and other forward-looking statements.

These forward-looking statements are based on Incyte's current expectations and are subject to risks and uncertainties that may cause actual results to differ materially, including risks and uncertainties regarding research and development of products and product candidates, determinations made by the FDA, EMA and other regulatory agencies, Incyte's dependence on its relationships with and changes in the plans of its collaboration partners; the efficacy or safety of Incyte's products, the acceptance of Incyte's products in the marketplace; market competition, unexpected variations in the demand for Incyte's products; the effects of announced or unexpected price regulation or limitations on reimbursement or coverage for Incyte's products, sales, marketing, manufacturing and distribution requirements, including Incyte's ability to successfully commercialize and build commercial infrastructure for newly approved products and any additional products that become approved; greater than expected expenses, including expenses relating to litigation or strategic activities, variations in foreign currency exchange rates; and other risks detailed in Incyte's reports filed with the Securities and Exchange Commission, including its annual report on Form 10-K and its quarterly report on Form 10-Q for the quarter ended March 31, 2026. Incyte disclaims any intent or obligation to update these forward-looking statements

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[1] Gong X, et al. ASH 2025. Poster 5045.

[2] Data on File. Incyte Corporation.

[3] Blood Cancer United. Myelofibrosis (MF). https://bloodcancerunited.org/blood-cancer/myeloproliferative-neoplasms-mpns/myelofibrosis-mf. Accessed May 2026.

[4] Blood Cancer United. Polycythemia vera (PV) https://bloodcancerunited.org/blood-cancer/myeloproliferative-neoplasms-mpns/polycythemia-vera-pv. Accessed May 2026.

[5] National Library of Medicine. The European Blood and Marrow Transplantation Textbook for Nurses: Under the Auspices of EBMT. https://www.ncbi.nlm.nih.gov/books/NBK543657/. Accessed May 2026.

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