Incyte Announces European Commission Approval of Jakavi® (ruxolitinib) as the First Post-Steroid Treatment for Acute and Chronic Graft-Versus-Host Disease

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- *Jakavi® (ruxolitinib) is the first JAK1/2 inhibitor available for patients in Europe who previously had no approved therapies for the treatment of steroid-refractory graft-versus-host disease (GVHD)[1,2]*
- *In clinical trials, Jakavi demonstrated superiority versus best available therapy in patients with steroid-refractory/dependent acute and chronic GVHD, with overall response rates of 62% vs. 39%, and 50% vs. 26% respectively[2,3]*
- *GVHD is a common and potentially life-threatening complication that arises in approximately half of patients following allogeneic stem cell transplants[4]*

WILMINGTON, Del.--(BUSINESS WIRE)--May 5, 2022-- Incyte (Nasdaq:INCY) today announced the European Commission (EC) has approved Jakavi® (ruxolitinib) for the treatment of patients aged 12 years and older with acute or chronic GVHD who have inadequate response to corticosteroids or other systemic therapies. Ruxolitinib is marketed as Jakavi by Novartis in Europe and as Jakafi® by Incyte in the United States.

“With the approval of this new indication for Jakavi, patients in Europe with acute or chronic GVHD who do respond to first-line steroid therapies have a new option that could redefine treatment for their condition,” said Peter Langmuir, M.D., Group Vice President, Oncology Targeted Therapies, Incyte. “Unfortunately, many people who receive allogenic stem cell transplants experience GVHD, and it is our hope that this Incyte-discovered medicine will make a significant impact for this patient population.”

The approval of Jakavi follows the positive opinion granted in March 2022 by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA), based on the Phase 3 REACH2 and REACH3 clinical studies in which Jakavi demonstrated superiority in overall response rate (ORR) compared to best available therapy (BAT). Results of REACH2 showed 62% ORR with Jakavi at Day 28, compared to 39% for BAT; and REACH3 demonstrated a significantly improved ORR at week 24 (50% vs. 26%) with a higher best ORR (76% vs. 60%) vs. BAT, among steroid-refractory/dependent chronic GVHD patients[2,3].

“Today, 30-60% of patients with GVHD do not respond to first-line steroid treatment, underscoring the need for new approaches to ensure long-term treatment goals are met,” said Robert Zeiser, M.D., University Hospital Freiburg, Department of Haematology, Oncology and Stem Cell Transplantation, Freiburg, Germany and lead investigator of the REACH trials. “The approval of Jakavi offers healthcare providers and patients with GVHD who remain dependent on or refractory to steroids a new way to manage this debilitating and life-threatening condition.”

GVHD occurs when donor cells see the recipient’s healthy cells as foreign and attack them. Symptoms of GVHD can appear in the skin, gastrointestinal tract, liver, mouth, eyes, genitals, lungs and joints. Approximately 50% of allogeneic stem cell transplant recipients will develop either acute or chronic GVHD. Both acute and chronic GVHD can be fatal and until now both have lacked an established standard of care for patients who do not adequately respond to first-line steroid treatment[1,4-9]. Currently, there are no other approved therapies for the treatment of GVHD after steroid failures in Europe[1,2].

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[10].

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

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.

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 Jakavi might provide a successful treatment for patients with acute or chronic graft-versus-host disease (GVHD), the Company's ongoing clinical development program for ruxolitinib, the REACH program and the Company's GVHD program generally 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; 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; greater than expected expenses; expenses relating to litigation or strategic activities; and other risks detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, including its annual report on Form 10-K for the year ended December 31, 2021. The Company disclaims any intent or obligation to update these forward-looking statements.

References:

[1] Jaglowski SM, et al. Graft-versus-Host Disease: Why Haven't We Made More Progress? Curr Opin Hematol. 2014;21(2):141-147

[2] Zeiser R, et al. Ruxolitinib for Glucocorticoid-Refractory Chronic Graft-versus-Host Disease (REACH3). New England Journal of Medicine; July 2021.

[3] Zeiser, R, et al. Ruxolitinib for Glucocorticoid-Refractory Acute Graft-versus-Host Disease (REACH2). New England Journal of Medicine. April 2020.

[4] Leukemia and Lymphoma Society. Graft-Versus-Host Disease Overview. 2021. Available at: https://www.lls.org/treatment/types-treatment/stem-cell-transplantation/graft-versus-host-disease

[5] Jakavi (ruxolitinib) Summary of Product Characteristics. Novartis Pharma AG; 2022.

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

[7] Zeiser R., et al. Pathophysiology of Chronic Graft-versus-Host Disease and Therapeutic Targets. N Engl J Med. 2017 Dec 28;377(26):2565-2579

[8] Jagasia MH, et al. National Institutes of Health Consensus Development Project on Criteria for Clinical Trials in Chronic Graft-versus-Host Disease: I. The 2014 Diagnosis and Staging Working Group report. Biol Blood Marrow Transplant. 2015.

[9] Martin PJ, Rizzo JD, Wingard JR, et al. First- and second-line systemic treatment of acute graft-versus-host disease: recommendations of the American Society of Blood and Marrow Transplantation. Biol Blood Marrow Transplant. 2012;18(8):1150-1163.

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

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