FDA Approves Jakafi® (ruxolitinib) for the Treatment of Patients with Acute Graft-Versus-Host Disease

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Jakafi is the first and only FDA-approved treatment for patientswith steroid-refractory acute graft-versus-host disease (GVHD)

WILMINGTON, Del.--(BUSINESS WIRE)--May 24, 2019-- Incyte Corporation (Nasdaq:INCY)today announced that the U.S. Food and Drug Administration (FDA) has approved Jakafi® (ruxolitinib) for the treatment of steroid-refractory acute GVHD in adult and pediatric patients 12 years and older. Jakafi is the first and only FDA-approved treatment for this indication.

“For the first time, patients with steroid-refractory acute GVHD, and the physicians that treat them, have an FDA-approved treatment for this serious disease,” stated Hervé Hoppenot, Chief Executive Officer, Incyte. “This approval is also an important milestone for Incyte, as it marks the third indication for Jakafi in the United States, further underscoring Incyte’s commitment to delivering innovative medicines for patients in need. We are proud of the impact Jakafi has had on patients’ lives to-date and are dedicated to advancing our ongoing research in JAK inhibition to serve more GVHD patients in the future.”

The approval was based on data from REACH1, an open-label, single-arm, multicenter study of Jakafi in combination with corticosteroids in patients with steroid-refractory grade II-IV acute GVHD. Of the 71 patients recruited into REACH1, 49 patients were refractory to steroids alone, 12 patients had received two or more prior anti-GVHD therapies and 10 patients did not otherwise meet the FDA definition of steroid-refractory. Jakafi was administered at 5 mg twice daily, and the dose could be increased to 10 mg twice daily after three days in the absence of toxicity.

The efficacy of Jakafi was evaluated based upon Day 28 overall response rate (ORR), defined as a complete response (CR), very good partial response or partial response based on the Center for International Blood and Marrow Transplant Research (CIBMTR) criteria. The Day 28 ORR in the 49 patients refractory to steroids alone was 57 percent with a CR rate of 31 percent. The most frequently reported adverse reactions among all 71 study participants were infections (55 percent) and edema (51 percent), and the most common laboratory abnormalities were anemia (75 percent), thrombocytopenia (75 percent) and neutropenia (58 percent).

GVHD is a condition that can occur after an allogeneic stem cell transplant (the transfer of stem cells from a donor) where 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 and chronic, that can affect multiple organ systems including the skin, gastrointestinal (digestive) tract and liver. Patients who develop steroid-refractory acute GVHD can progress to severe disease, with one-year mortality rates of approximately 70 percent.[1]

“Every year in the United States, about half of the people who develop acute GVHD do not respond adequately to steroids, making it an extremely challenging disease to treat,” said Madan Jagasia, M.B.B.S., M.S., M.M.H.C., a lead investigator on the REACH1 trial and Professor of Medicine, Vanderbilt University Medical Center, Department of Medicine, Division of Hematology-Oncology and Chief Medical Officer, Vanderbilt-Ingram Cancer Center. “While allogeneic stem cell transplants have the potential to transform people’s lives, the onset of acute GVHD can significantly impact their prognosis. I am excited that we now have Jakafi as a new treatment option for acute GVHD patients that do not respond to corticosteroids who, until now, have had limited choices.”

Previously, the FDA granted Jakafi Breakthrough Therapy Designation and Orphan Drug Designation for the treatment of patients with steroid-refractory acute GVHD, and the supplemental New Drug Application (sNDA) was reviewed under the FDA’s Priority Review program.

Jakafi will be made available to appropriate patients with steroid-refractory acute GVHD immediately. 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 1-855-4-Jakafi (855-452-5234).

About REACH

The REACH clinical trial program is evaluating Jakafi in patients with steroid-refractory GVHD. The REACH program includes the Incyte-sponsored REACH1 trial, a prospective, open-label, single-cohort, multicenter, pivotal Phase 2 trial (NCT02953678) evaluating Jakafi in combination with corticosteroids in patients with steroid-refractory grade II-IV acute GVHD. For more information about the REACH1 trial, please visit https://clinicaltrials.gov/show/NCT02953678.

The REACH clinical program also includes the collaborative Novartis-sponsored randomized pivotal Phase 3 trials in patients with steroid-refractory acute GVHD (REACH2) and steroid-refractory chronic GVHD (REACH3). Results from both REACH2 and REACH3 are currently expected before the end of 2019.

About Jakafi® (ruxolitinib)

Jakafi is a first-in-class JAK1/JAK2 inhibitor approved by the U.S. FDA for treatment of steroid-refractory acute GVHD 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 as well as intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF in

adults.

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 your platelet, red blood cell, or white blood cell counts to be lowered. If you develop bleeding, stop taking Jakafi and call your healthcare provider. Your healthcare provider will perform blood tests 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.

Skin cancers: Some people who take Jakafi have developed certain types of non-melanoma skin cancers. Tell your healthcare provider if you develop any new or changing skin lesions.

Increases in cholesterol: You may have changes in your blood cholesterol levels. Your healthcare provider will do blood tests to check your cholesterol levels during your treatment with Jakafi.

The most common side effects of Jakafi include: for certain types of MF and PV - low platelet count, low red blood cell count, bruising, dizziness, and headache; and for acute GVHD – low red blood cell counts, low platelet counts, low white blood cell counts, infections and fluid retention.

These are not all the possible side effects of Jakafi. Ask your pharmacist or healthcare provider for more information. Tell your healthcare provider about any side effect that bothers you or that does not go away.

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 tuberculosis (TB), or have been in close contact with someone who has TB, have or had hepatitis B, have or had liver or kidney problems, are on dialysis, have a high level of fat in your blood (high blood cholesterol or triglycerides), had skin cancer or have any other medical condition. Take Jakafi exactly as your healthcare provider tells you. Do not change 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 breast-feed during treatment with Jakafi and for 2 weeks after the final dose.

Full Prescribing Information, which includes a more complete discussion of the risks associated with Jakafi, is available at www.jakafi.com.

About Incyte

Incyte Corporation is a Wilmington, Delaware-based biopharmaceutical company focused on the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit the Company's web site at www.incyte.com.

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Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this release contain predictions, estimates and other forward-looking statements, including statements regarding efforts to advance the Company’s ongoing research in JAK inhibition and to help more GVHD patients in the future, the potential efficacy, safety and therapeutic value of Jakafi® (ruxolitinib) in patients with steroid-refractory GVHD and expected timing of initial results of the REACH2 and REACH3 trials. 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 those risks detailed from time to time in Incyte’s reports filed with the Securities and Exchange Commission, including its Form 10-Q for the quarter ending March 31, 2019. Incyte disclaims any intent or obligation to update these forward-looking statements.

[1] Shapira MY, Klimov A, Vipul S, et al. Regional intra-arterial steroid treatment in 120 patients with steroid-resistant or -dependent GvHD. Bone Marrow Transplant. 2017;52(10):1416-1422.

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