

Incyte Announces First Data from REACH3 Trial Showing Ruxolitinib (Jakafi®) Significantly Improved Outcomes in Patients with Steroid-Refractory or Steroid-Dependent Chronic Graft-Versus-Host Disease

December 4, 2020

- Results of REACH3 trial also demonstrate significant improvements in failure-free survival (FFS) and patient-reported symptoms¹
- Findings from the study are being presented at ASH 2020, and complement previously-reported positive results for Jakafi in steroid-refractory acute graft-versus-host disease (GVHD)²
- Chronic GVHD is a life-threatening complication of stem cell transplants and half of patients become steroid refractory/dependent^{3,4}
- Investor conference call and webcast scheduled for Monday, December 7, 2020 at 10:00 a.m. ET (7:00 a.m. PT)

WILMINGTON, Del.--(BUSINESS WIRE)-- Incyte (Nasdaq:INCY) today announced that detailed results from the pivotal Phase 3 REACH3 study demonstrate Jakafi® (ruxolitinib) significantly improved outcomes across a range of efficacy measures in patients with steroid-refractory or steroid-dependent chronic graft-versus-host disease (GVHD) compared to best available therapy (BAT)¹. The results of REACH3, the first successful, randomized Phase 3 trial in chronic GVHD, were highlighted in a press briefing today and will be presented during the 62nd American Society of Hematology Annual Meeting & Exposition (ASH 2020). REACH3 is jointly sponsored by Incyte and Novartis.

"The results from this large, randomized study further emphasize the role Jakafi can play as a meaningful option for patients with chronic GVHD, for whom new treatments are urgently needed," said Peter Langmuir, M.D., Group Vice President, Oncology Targeted Therapies, Incyte. "These data are important for patients living with GVHD and their physicians as they represent the continued success of Jakafi in the chronic form of the disease, a historically difficult-to-treat condition."

In REACH3, patients treated with Jakafi achieved significantly greater overall response rate (ORR) compared to BAT (49.7% vs. 25.6%; $p < 0.0001$)⁵ at Week 24, the primary endpoint of the study⁶. Jakafi also demonstrated statistically significant and clinically meaningful improvements in key secondary endpoints:

- Patients receiving Jakafi had a significant improvement in failure-free survival (FFS; defined as time to the earliest recurrence of the underlying disease, the start of new systemic treatment for chronic GVHD, or death) versus patients receiving BAT (median FFS not yet reached vs. 5.7 months; hazard ratio, 0.37, 95% CI, 0.27-0.51; $p < 0.0001$)¹.
- Patients treated with Jakafi also had greater improvements in patient-reported symptoms than those treated with BAT (24.2% vs. 11.0%; $p = 0.0011$), as measured by the rate of responders who achieved a reduction of ≥ 7 points of total symptom score (TSS) from baseline of the modified Lee Symptom Score (mLSS)¹.
- Additionally, best overall response (BOR) rate, defined as any response up to week 24, was achieved in 76.4% of patients in the Jakafi arm compared to 60.4% in the BAT arm (odds ratio [OR], 2.17; 95% CI, 1.34-3.52). The median duration of response was 6.2 months in the BAT arm, but was not yet reached in the Jakafi arm¹.

No new safety signals were observed in REACH3, and adverse events (AEs) attributable to treatment were consistent with the known safety profile of Jakafi. The most common AEs in the Jakafi vs. BAT arms were anemia (29.1% vs. 12.7%), hypertension (15.8% vs. 12.7%) and pyrexia (15.8% vs. 9.5%). While 37.6% and 16.5% of patients required Jakafi and BAT dose modifications, respectively, the number of patients who discontinued treatment due to AEs was low (16.4% and 7%, respectively). Mortality rates were similar across treatment arms (19% vs. 16% BAT)¹. Deaths reported as primarily due to chronic GVHD were slightly higher for Jakafi.

"The damaging and sometimes deadly effects of chronic GVHD following stem cell transplant present significant treatment challenges, particularly for the nearly half of patients who do not adequately respond to steroid treatment," said Dr. Robert Zeiser, University Hospital Freiburg, Department of Haematology, Oncology and Stem Cell Transplantation, Freiburg, Germany. "Based on the compelling REACH3 results, we now have a potential new standard of care for these patients."

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, which occurs within 100 days of transplant, and chronic, which occurs after 100 days of transplant³. GVHD can affect multiple organ systems including the skin, gastrointestinal (digestive) tract and liver.

In 2019, Jakafi® (ruxolitinib) was approved by the U.S. Food and Drug Administration for the treatment of steroid-refractory acute GVHD in adult and pediatric patients 12 years and older, based on the positive results of the Phase 2 REACH1 trial⁶. Jakafi is marketed by Incyte in the U.S.; ruxolitinib (Jakafi®) is licensed to Novartis ex-U.S.

About REACH3

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

The primary endpoint is overall response rate (ORR) at Day 1 of the Cycle 7 (Day 168) visit, defined as the percentage of participants demonstrating a complete or partial response. Secondary endpoints include change in the modified Lee chronic GVHD symptom scale score at Day 1 of Cycle 7, rate of failure-free survival (FFS) up to 36 months, best overall response (BOR), duration of response (DoR), overall survival (OS), among others. For more information about the study, please visit <https://clinicaltrials.gov/ct2/show/NCT03112603>.

About REACH

The REACH clinical trial program evaluating ruxolitinib in patients with steroid-refractory GVHD includes the randomized pivotal Phase 3 REACH2 and REACH3 trials, conducted in collaboration with Novartis.

The REACH program was initiated with 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 study, including trial results, please visit <https://clinicaltrials.gov/show/NCT02953678>.

About Jakafi® (ruxolitinib)

Jakafi is a first-in-class 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, in adults with intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF and for the treatment of steroid-refractory acute GVHD in adult and pediatric patients 12 years and older.

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 or low red blood cell counts, bruising, dizziness, headache, and diarrhea; and for acute GVHD - low platelet, red or 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.

Conference Call Information

Incyte will host an investor conference call and webcast at 10:00 a.m. ET (7:00 a.m. PT) on Monday, December 7, 2020—the call and webcast can be accessed via the [Events and Presentations](#) tab of the Investor section of incyte.com and it will be available for replay for 90 days.

To access the conference call, please dial 877-407-3042 for domestic callers or +1 201-389-0864 for international callers. When prompted, provide the conference identification number, 13713399.

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 about the REACH3 data, the effect

of the REACH3 results on patients with GVHD, and the overall REACH 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; determinations made by the FDA; 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 quarterly report on Form 10-Q for the quarter ended September 30, 2020. The Company disclaims any intent or obligation to update these forward-looking statements.

¹ Zeiser R, M.D., et al. Ruxolitinib (RUX) vs Best Available Therapy (BAT) in Patients with Steroid-Refractory/Steroid-Dependent Chronic Graft-vs-Host Disease (cGVHD): Primary Findings from the Phase 3, Randomized REACH3 Study. 62nd American Society of Hematology Annual Meeting & Exposition (ASH). Abstract #77.

² Zeiser R, M.D., et al. Ruxolitinib for Glucocorticoid-Refractory Acute Graft-versus-Host Disease. New England Journal of Medicine. 2020;382:1800-1810.

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

⁴ Jaglowski SM, et al. Graft-versus-Host Disease: Why Haven't We Made More Progress? Curr Opin Hematol. 2014;21(2):141-147.

⁵ Descriptive P value given for ORR at the primary analysis as the efficacy boundary was crossed at the interim analysis (ORR, P = 0.0003).

⁶ Jakafi (ruxolitinib) tablets: Prescribing Information. U.S. Food and Drug Administration; May 2019.



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