Incyte Announces Pivotal REACH2 Study Data Published in NEJM Highlight Superior Efficacy of Ruxolitinib (Jakafi®) versus Best Available Therapy in Patients with Acute Graft-Versus-Host Disease

April 22, 2020

- Phase 3 REACH2 data demonstrate that ruxolitinib (Jakafi®) improves outcomes across a range of efficacy measures in patients with steroid-refractory acute graft-versus-host disease (GVHD) compared to best available therapy (BAT)

- Results show a significantly greater overall response rate (ORR) in patients treated with ruxolitinib (62%) compared to BAT (39%) [1,2]

- GVHD is a serious and common complication of allogeneic stem cell transplants with a one-year mortality rate as high as 80% in patients who develop acute GVHD[3-5]

- The results, published in The New England Journal of Medicine, *were also selected for an oral presentation during the Presidential Symposium at the European Society for Blood and Marrow Transplantation (EBMT) Annual Meeting to be held 30 August to 2 September in Madrid, Spain*

WILMINGTON, Del.--(BUSINESS WIRE)--Apr. 22, 2020-- Incyte (Nasdaq:INCY) today announced that data from the Phase 3 REACH2 study have been published in *The New England Journal of Medicine* demonstrating that ruxolitinib (Jakafi®) improves outcomes across a range of efficacy measures in patients with steroid-refractory acute graft-versus-host disease (GVHD) compared to best available therapy (BAT). The results of REACH2, the first Phase 3 study of ruxolitinib in acute GVHD to have met its primary endpoint, reinforce findings from the previously-reported Phase 2 REACH1 study.

In REACH2, patients treated with ruxolitinib experienced a significantly greater overall response rate (ORR) vs. BAT (62% vs. 39%; p<0.001) at Day 28, the primary endpoint of the study. For the key secondary endpoints, patients treated with ruxolitinib maintained significantly higher durable ORR (40% vs. 22%; p<0.001) at Day 56. In addition, ruxolitinib was associated with longer median failure free survival (FFS) than BAT (5.0 months vs. 1.0 months; hazard ratio 0.46, 95% CI, 0.35 to 0.60) and showed a positive trend with other secondary endpoints, including duration of response[1,2].

No new safety signals were observed, and the ruxolitinib safety profile in REACH2 was consistent with that seen in previously reported studies in steroid-refractory acute GVHD. The most frequently reported adverse events among study participants were thrombocytopenia and anemia. While 38% and 9% of patients required ruxolitinib and BAT dose modifications, the number of patients who discontinued treatment due to AEs was low (11% and 5%, respectively)[1,2].

"The results from the REACH2 study reinforce findings from the pivotal REACH1 trial and demonstrate the potential that ruxolitinib has to effectively and safely improve outcomes for patients with GVHD," said Peter Langmuir, M.D., Group Vice President, Oncology Targeted Therapies, Incyte. "We are committed to continuing our research in GVHD with the goal of providing more effective treatment options for patients living with this disease, and look forward to the results of the REACH3 study in steroid-refractory chronic GVHD later this year."

The REACH2 data were also accepted as an oral presentation as part of the Presidential Symposium at the European Society for Blood and Marrow Transplantation (EBMT) Annual Meeting to be held 30 August to 2 September in Madrid, Spain.

"Patients with acute graft-versus-host disease face life-threatening challenges with limited treatment options, particularly for the nearly half of individuals who do not respond to initial steroid therapy," said Robert Zeiser, University Hospital Freiburg, Department of Haematology, Oncology and Stem Cell Transplantation, Freiburg, Germany. "These new data from REACH2 showing superiority of ruxolitinib over current standard-of-care therapies add to a growing body of evidence on how targeting the JAK pathway can be an effective strategy in this difficult-to-treat condition."

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 trial[6]. The Phase 3 REACH3 study in patients with steroid-refractory chronic GVHD is ongoing and results are expected in the second half of this year. Jakafi is marketed by Incyte in the U.S.; ruxolitinib (Jakavi®) is licensed to Novartis ex-U.S.

The NEJM publication of the REACH2 results is available online.

About REACH2

REACH2 (NCT02913261), 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 acute GVHD.

The primary endpoint was overall response rate (ORR) at Day 28, defined as the proportion of patients demonstrating a best overall response (complete response or partial response). Secondary endpoints include durable ORR at Day 56, ORR at Day 14, duration of response, overall survival and event-free survival, among others. For more information about the study, please visit https://clinicaltrials.gov/ct2/show/NCT02913261.

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 ongoing REACH3 trial is evaluating patients with steroid-refractory chronic GVHD with results expected later this year. For more information about the REACH3 study, please visit https://clinicaltrials.gov/ct2/show/NCT03112603.

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.

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 REACH2 data, when results from the REACH3 study will be available, the effect of the REACH2 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 Form 10-K for the year ended December 31, 2019. The Company disclaims any intent or obligation to update these forward-looking statements.

References

1. Robert Zeiser, et al. Randomized Phase 3 Trial Evaluating the Efficacy and Safety of Ruxolitinib vs Best Available Therapy in Patients with Steroid-Refractory Acute Graft vs Host Disease (aGVHD). The European Society for Blood and Marrow Transplantation (EBMT) Annual Meeting. 2020. Abstract GS2-8.

2. Robert Zeiser, et al. A Phase 3 Randomized Trial of Ruxolitinib for Steroid-Refractory Acute Graft-Versus-Host Disease. New England Journal of Medicine. 2020.
3. Von Dalowski F, et al. Mesenchymal Stromal Cells for Treatment of Acute Steroid-Refractory Graft Versus Host Disease: Clinical Responses and Long-Term Outcome. Stem Cells, 2016 34(2): 357-366. doi.org/10.1002/stem.2224
4. Shapira MY, et al. Regional intra-arterial steroid treatment in 120 patients with steroid-resistant or -dependent GvHD. Bone Marrow Transplant. 2017 52(10): 1416-1422. doi.org/10.1038/bmt.2017.120
5. Pidala J, et al. Mycophenolate mofetil for the management of steroid-refractory acute graft vs host disease. Bone Marrow Transplant. 2010 45(5): 919-924. doi.org/10.1038/bmt.2009.252
6. Jakafi® (ruxolitinib) tablets: Prescribing Information. U.S. Food and Drug Administration; May 2019

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Source: Incyte