Incyte Provides Update on Interim Analysis of Phase 3 LIMBER-304 Study of Parsaclisib and Ruxolitinib in Patients with Myelofibrosis

March 3, 2023

- *Independent data monitoring committee advises study unlikely to meet primary endpoint, leading to decision to discontinue the study*

WILMINGTON, Del.--(BUSINESS WIRE)--Mar. 3, 2023-- Incyte (Nasdaq:INCY) today announced that it will discontinue the Phase 3 LIMBER-304 trial following results of a pre-planned interim analysis conducted by an independent data monitoring committee (IDMC) indicating that the study is unlikely to meet the primary endpoint in the intent-to-treat patient population. The recommendation to stop the study was not due to safety. LIMBER-304 is a randomized, double-blind study evaluating the efficacy and safety of parsaclisib plus ruxolitinib (Jakafi®) versus placebo plus ruxolitinib in adult (age ≥18 years) patients living with myelofibrosis (MF) who have an inadequate response to ruxolitinib monotherapy.

While further review of the data is conducted, Incyte will inform investigators of the results and work with them to appropriately conclude the study in a manner consistent with the best interest of each patient. Data from this study will be submitted for presentation at an upcoming scientific meeting.

The primary endpoint of LIMBER-304 (NCT04551053) was the proportion of patients achieving targeted reduction in spleen volume as measured by magnetic resonance imaging or computed tomography. Secondary endpoints included the proportion of patients who have a targeted reduction in Total Symptom Score (TSS), change in TSS, time to the first ≥50% reduction in TSS, overall survival, number of treatment emergent adverse events, time of onset of targeted reduction in spleen volume and duration of maintenance of targeted reduction in spleen volume.

About LIMBER

Incyte is a leader in the discovery and development of therapies for patients with myeloproliferative neoplasms (MPNs) and graft-versus-host disease (GVHD). The LIMBER clinical trial program is designed to evaluate multiple monotherapy and combination strategies to improve and expand treatments for patients with MPNs and GVHD. These include ruxolitinib-based combinations with BET and ALK2, new therapeutic options including axatilimab and novel targets such as mutant CALR.

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 the presentation of data from the Company's ongoing clinical development program for parsaclisib and ruxolitinib, development plans for ruxolitinib and further development in myelofibrosis, 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 annual report for the year ended December 31, 2022. The Company disclaims any intent or obligation to update these forward-looking statements.

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