Incyte Provides Update on Early Phase MRGPRX2 and MRGPRX4 Programs

November 18, 2024

WILMINGTON, Del.--(BUSINESS WIRE)--Nov. 18, 2024-- Incyte (Nasdaq:INCY) today announced that it will pause enrollment in the ongoing Phase 2 study of MRGPRX2 (INCB000262) in chronic spontaneous urticaria (CSU). The decision was made following the observation of certain in vivo preclinical toxicology findings.

These data have been shared with the U.S. Food and Drug Administration (FDA) and Incyte will work closely with the FDA to determine next steps.

Enrollment in the other INCB000262 proof-of-concept studies is complete and data from all clinical studies will help inform its future development and guide the potential development of back-up molecules.

In addition, data from the Phase 2 study evaluating MRGPRX4 (INCB000547) in cholestatic pruritus (CP) does not support further development.

About Incyte

A global biopharmaceutical company on a mission to *Solve On.*, Incyte follows the science to find solutions for patients with unmet medical needs. Through the discovery, development and commercialization of proprietary therapeutics, Incyte has established a portfolio of first-in-class medicines for patients and a strong pipeline of products in Oncology and Inflammation & Autoimmunity. Headquartered in Wilmington, Delaware, Incyte has operations in North America, Europe and Asia.

For additional information on Incyte, please visit Incyte.com or follow us on social media: LinkedIn, X, Instagram, Facebook, YouTube.

Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release contain predictions, estimates and other forward-looking statements, including any discussion of the ongoing Phase 2 study of MRGPRX2 (INCB000262), Incyte's decision to pause enrollment in that study, Incyte's intent to work with FDA to determine next steps, and future development of INCB000262 and other back-up molecules.

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 unanticipated developments in and risks related to: further research and development and the possibility that results of clinical trials will be negative and/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; determinations made by FDA and other regulatory agencies; the efficacy or safety of Incyte's products; the acceptance of Incyte's products in the marketplace; market competition; unexpected variations in the supply of and/or demand for Incyte's products; the effects of announced or unexpected price regulation or limitations on reimbursement or coverage for Incyte's products; sales, marketing, manufacturing and distribution requirements, including Incyte's ability to successfully commercialize and build commercial infrastructure for newly approved products and any additional products that become approved; greater than expected expenses, including expenses relating to litigation or strategic activities; variations in foreign currency exchange rates; and other risks detailed in Incyte's reports filed with the Securities and Exchange Commission, including its quarterly report on form 10-Q for the quarter ended September 30, 2024. Incyte disclaims any intent or obligation to update these forward-looking statements.

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