Incyte Highlights Commercial Growth, Clinical Progress and 2025 Milestones at the 43rd Annual J.P. Morgan Healthcare Conference

January 13, 2025

- 2025 will be a transformational year for Incyte with multiple significant milestones, including four potential launches, four pivotal trial readouts, seven proof of concept data readouts and at least three Phase 3 study initiations

- Well-positioned for long-term growth, the Company has the potential to deliver more than 10 high impact launches across its portfolio by 2030

WILMINGTON, Del.--(BUSINESS WIRE)--Jan. 13, 2025-- Incyte (Nasdaq:INCY) will provide an update on commercial growth, clinical progress and significant 2025 catalysts during a presentation today at 10:30 a.m. PT at the 43rd Annual J.P. Morgan Healthcare Conference in San Francisco.

“With significant advancements being made across our portfolio, 2025 will be a transformational year not only for Incyte, but also for the patients we serve,” said Hervé Hoppenot, Chief Executive Officer, Incyte. “We have several novel medicines in development that can potentially address significant patient needs, and we remain on track to deliver numerous first- or best-in-class high impact launches from our pipeline by 2030.”

Today’s presentation will highlight:

- The launch of Niktimvo™ (axatilimab-csfr) for patients living with chronic graft-versus-host disease (GVHD) and ongoing studies of axatilimab in additional indications.
- Near-term opportunities for tafasitamab (Monjuvi®) following positive results from the Phase 3 inMIND trial in patients with relapsed/refractory follicular lymphoma (FL), as well as the anticipated data evaluating tafasitamab in first line diffuse large B-cell lymphoma (DLBCL).
- The potential of povorcitinib (INCB54707), an investigational oral JAK1 inhibitor, to establish best-in-class efficacy across numerous indications with high unmet needs, including hidradenitis suppurativa (HS).
- Incyte’s mCALR-targeting molecule (INCA33989) and its potential to be a first-in-class targeted therapy for mCALR positive myelofibrosis (MF) and essential thrombocythemia (ET) patients.
- The development path for Incyte’s CDK2 inhibitor (INCB123667) and its potential to become a foundational treatment for patients with ovarian cancer.

The J.P. Morgan Healthcare Conference presentation and Q&A session can be accessed at investor.incyte.com. A replay will be archived on the Company’s website for 30 days following the presentation.

About Niktimvo™ (axatilimab-csfr)

Niktimvo (axatilimab-csfr) is a first-in-class anti-CSF-1R antibody approved for use in the U.S. for the treatment of chronic graft-versus-host disease (cGVHD) after failure of at least two prior lines of systemic therapy in adult and pediatric patients weighing at least 40 kg (88.2 lbs).

In 2016, Syndax licensed exclusive worldwide rights to develop and commercialize axatilimab from UCB. In September 2021, Syndax and Incyte entered into an exclusive worldwide co-development and co-commercialization license agreement for axatilimab in cGVHD and any future indications.

Axatilimab is being studied in frontline combination trials in chronic GVHD – a Phase 2 combination trial with ruxolitinib (NCT06388564) and a Phase 3 combination trial with steroids are expected to initiate by year end. Axatilimab is also being studied in an ongoing Phase 2 trial in patients with idiopathic pulmonary fibrosis (NCT06132256).

Niktimvo is a trademark of Incyte.

About Tafasitamab (Monjuvi®)

Tafasitamab (Monjuvi®) is a humanized Fc-modified cytolytic CD19 targeting monoclonal antibody. In 2010, MorphoSys licensed exclusive worldwide rights to develop and commercialize tafasitamab from Xencor, Inc. Tafasitamab incorporates an XmAb® engineered Fc domain, which mediates B-cell lysis through apoptosis and immune effector mechanism including Antibody-Dependent Cell-Mediated Cytotoxicity (ADCC) and Antibody-Dependent Cellular Phagocytosis (ADCP). MorphoSys and Incyte entered into: (a) in January 2020, a collaboration and licensing agreement to develop and commercialize tafasitamab globally; and (b) in February 2024, an agreement whereby Incyte obtained exclusive rights to develop and commercialize tafasitamab globally.

In the United States, Monjuvi® (tafasitamab-cxix) received accelerated approval by the U.S. Food and Drug Administration in combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant (ASCT). In Europe, Minjuvi® (tafasitamab) received conditional Marketing Authorization from the European Medicines Agency in combination with lenalidomide, followed by Minjuvi monotherapy, for the treatment of adult patients with relapsed or refractory DLBCL who are not eligible for ASCT.

XmAb® is a registered trademark of Xencor, Inc.

Monjuvi, Minjuvi, the Minjuvi and Monjuvi logos and the “triangle” design are registered trademarks of Incyte.

About Povorcitinib (INCB54707)

Povorcitinib (INCB54707) is an oral small-molecule JAK1 inhibitor currently in Phase 3 clinical trials for hidradenitis suppurativa (HS) and vitiligo. A Phase 3 trial is being planned for prurigo nodularis (PN). Phase 2 studies of povorcitinib in PN, asthma and chronic spontaneous urticaria are also ongoing.

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.

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 Incyte's clinical development pipeline, Incyte's potential for commercial growth, clinical progress and achievement of milestones in 2025 and longer term, whether or when any development compounds or combinations will be approved or commercially available for use in humans anywhere in the world outside of the already approved indications in specific regions, and Incyte's goal of improving the lives of patients, contain predictions, estimates, and other forward-looking statements.

These forward-looking statements are based on our current expectations and are 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 and the ability to enroll subjects in accordance with planned schedules; determinations made by FDA and regulatory agencies outside of the United States; the efficacy or safety of our products; the acceptance of our products in the marketplace; market competition; unexpected variations in the demand for our products and the products of our collaboration partners; the effects of announced or unexpected price regulation or limitations on reimbursement or coverage for our products; sales, marketing, manufacturing, and distribution requirements, including our ability to successfully commercialize and build commercial infrastructure for newly approved products and any additional new products that become approved; and other risks detailed from time to time in our reports filed with the U.S. Securities and Exchange Commission, including our annual report on Form 10-K and our quarterly report on Form 10-Q for the quarter ended September 30, 2024. We disclaim any intent or obligation to update these forward-looking statements.

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