Incyte to Spotlight New Data, Including a Late Breaking Oral Presentation for Tafasitamab in Follicular Lymphoma, at the 2024 ASH Annual Meeting

November 25, 2024

- Twenty presentations, including late-breaking, oral and poster presentations, highlight advances across seven of the company's medicines

- Late-breaking data presentation at ASH will feature results from the Phase 3 inMIND study evaluating tafasitamab in follicular lymphoma (FL); data to be highlighted during ASH press program

- Incyte to host virtual analyst and investor event on Thursday, December 12, 2024, from 4:00-5:00 p.m. ET to discuss key data presentations from ASH

WILMINGTON, Del.--(BUSINESS WIRE)--Nov. 25, 2024-- Incyte (Nasdaq: INCY) today announced that the Company will present new data from across its oncology portfolio at the 2024 American Society of Hematology (ASH) Annual Meeting in San Diego.

"These data illustrate our innovative approach that aims to identify new and best-in-class treatments for patients with a range of cancers," said Pablo J. Cagnoni, M.D., President and Head of Research and Development, Incyte. "At ASH, we're presenting comprehensive data from our Phase 3 inMIND trial in relapsed or refractory follicular lymphoma. This late-breaking presentation provides valuable insights into the potential role of tafasitamab in improving outcomes for FL patients who currently face limited effective treatment options."

Details on key abstracts accepted for presentation include:

ASH Abstracts

Late-Breaking Oral Presentation

Tafasitamab
Tafasitamab Plus Lenalidomide and Rituximab for Relapsed or Refractory Follicular Lymphoma: Results from a Phase 3 Study (inMIND)
Session: Late-Breaking Abstracts Session. Publication Number: LBA-1. December 10, 10:30 a.m. ET (7:30 a.m. PT).

Oral Presentations

Axatilimab
Dynamics of Overall and Organ-Specific Responses to Axatilimab in Chronic Graft-Versus-Host Disease: Analysis from the AGAVE-201 Study
Session: 722. Allogeneic Transplantation: Acute and Chronic GVHD and Immune Reconstitution: Predicting and Treating Acute and Chronic GVHD. Publication Number: 98. December 7, 12:45 p.m. ET (9:45 a.m. PT).

INCB057643
Safety and Efficacy of Bromodomain and Extra-Terminal Inhibitor INCB057643 in Patients with Relapsed or Refractory Myelofibrosis and Other Advanced Myeloid Neoplasms: A Phase 1 Study
Session: 634. Myeloproliferative Syndromes: Clinical and Epidemiological: Advancing Treatment Paradigms in Myeloproliferative Neoplasms and Mastocytosis. Publication Number: 658. December 8, 8:15 p.m. ET (5:15 p.m. PT).

Poster Presentations

Ruxolitinib (Myeloproliferative Neoplasms [MPN])
Clinical and Molecular Characterization of Disease Progression in Patients (Pts) with Low-Risk Myelofibrosis (MF) Enrolled in the MOST Study
Poster Session: 631. Myeloproliferative Syndromes and Chronic Myeloid Leukemia: Basic and Translational: Poster II. Publication Number: 3136. December 8, 9:00 p.m. – 11:00 p.m. ET. (6:00 p.m. – 8:00 p.m. PT).

Molecular Predictors of Disease Progression to Myelofibrosis (MF) in Patients (Pts) with Polycythemia Vera (PV) Enrolled in REVEAL
Poster Session: 631. Myeloproliferative Syndromes and Chronic Myeloid Leukemia: Basic and Translational: Poster II. Publication Number: 3145. December 8, 9:00 p.m. – 11:00 p.m. ET. (6:00 p.m. – 8:00 p.m. PT).

Real-World Treatment Patterns and Blood Count Control in Patients with Polycythemia Vera Who Switched From Hydroxyurea to Ruxolitinib
Poster Session: 908. Outcomes Research: Myeloid Malignancies: Poster II. Publication Number: 3813. December 8, 9:00 p.m. – 11:00 p.m. ET. (6:00 p.m. – 8:00 p.m. PT).

Clinical Outcomes in Patients with Myelofibrosis Treated with Ruxolitinib and Anemia-Supporting Medications
Poster Session: 634. Myeloproliferative Syndromes: Clinical and Epidemiological: Poster III. Publication Number: 4546. December 9, 9:00 p.m. – 11:00 p.m. ET. (6:00 p.m. – 8:00 p.m. PT).

Ruxolitinib (Graft-versus-host Disease [GVHD])
Real-World Ruxolitinib and Corticosteroid Treatment Patterns in Patients with Chronic Graft-Versus-Host Disease in the United States
Poster Session: 722. Allogeneic Transplantation: Acute and Chronic GVHD and Immune Reconstitution: Poster III. Publication Number: 4900. December 9, 9:00 p.m. – 11:00 p.m. ET. (6:00 p.m. – 8:00 p.m. PT).

Tafasitamab

Real-World Effectiveness of Tafasitamab (Tafa) for the Treatment of Relapsed/Refractory Diffuse Large B-Cell Lymphoma (R/R DLBCL) in the United States
Poster Session: 906. Outcomes Research: Lymphoid Malignancies Excluding Plasma Cell Disorders: Poster I. Publication Number: 2375. December 7, 8:30 p.m. – 10:30 p.m. ET (5:30 p.m. – 7:30 p.m. PT).

Maintenance of CD19 Expression After Tafasitamab Treatment in Patients with Relapsed/Refractory Diffuse Large B-Cell Lymphoma (R/R DLBCL) From Clinical Trial and Real-World Settings
Poster Session: 622. Lymphomas: Translational – Non-Genetic: Poster II. Publication Number: 2991. December 8, 9:00 p.m. – 11:00 p.m. ET. (6:00 p.m. – 8:00 p.m. PT).

Axatilimab
Axatilimab Abrogates Inflammatory Cytokines and Chemokines and Interrupts the Differentiation of Monocytes to Macrophages, a Pathogenic Driver of Inflammation and Fibrosis in cGVHD
Poster Session: 201. Granulocytes, Monocytes, and Macrophages: Poster I. Publication Number: 1147. December 7, 8:30 p.m. – 10:30 p.m. ET (5:30 p.m. – 7:30 p.m. PT).

Exposure-Response Relationships for Axatilimab, a Humanized Monoclonal Antibody Targeting CSF-1R, in Patients with Chronic Graft-Versus-Host Disease
Poster Session: 722. Allogeneic Transplantation: Acute and Chronic GVHD and Immune Reconstitution: Poster I. Publication Number: 2140. December 7, 8:30 p.m. – 10:30 p.m. ET (5:30 p.m. – 7:30 p.m. PT).

Real-World Patient Characteristics and Treatment Patterns in Patients with Chronic Graft-Versus-Host Disease Receiving Belumosudil in the United States
Poster Session: 722. Allogeneic Transplantation: Acute and Chronic GVHD and Immune Reconstitution: Poster II. Publication Number: 3522. December 8, 9:00 p.m. – 11:00 p.m. ET. (6:00 p.m. – 8:00 p.m. PT).

Ponatinib
The Impact of Ponatinib on Pregnancy Outcomes
Poster Session: 908. Outcomes Research: Myeloid Malignancies: Poster I. Publication Number: 2435. December 7, 8:30 p.m. – 10:30 p.m. ET (5:30 p.m. – 7:30 p.m. PT).

Long-Term Safety and Effectiveness of Ponatinib Treatment in Patients with TKI Intolerance: Subgroup Analysis of the Observational Study of Ponatinib Treatment in Patients with CML in Italy (OITI)
Poster Session: 908. Outcomes Research: Myeloid Malignancies: Poster I. Publication Number: 2427. December 7, 8:30 p.m. – 10:30 p.m. ET (5:30 p.m. – 7:30 p.m. PT).

Ponatinib Safety Profile: An Analysis of 10-Years of Real-World Experience
Poster Session: 908. Outcomes Research: Myeloid Malignancies: Poster II. Publication Number: 3816. December 8, 9:00 p.m. – 11:00 p.m. ET. (6:00 p.m. – 8:00 p.m. PT).

INCB057643
Machine Learning in Predicting Longitudinal Platelet Counts: Applications in Dose Optimization
Poster Session: 803. Emerging Tools, Techniques, and Artificial Intelligence in Hematology: Poster III. Publication Number: 4985. December 9, 9:00 p.m. – 11:00 p.m. ET. (6:00 p.m. – 8:00 p.m. PT).

More information regarding the 2024 ASH Annual Meeting can be found on their website: https://www.hematology.org/meetings/annual-meeting/schedule-and-program.

All sessions will be broadcast virtually, and access to the meeting's virtual platform is included with registration.

Conference Call and Webcast
Incyte will hold a conference call and webcast on Thursday, December 12, 2024, from 4:00-5:00 p.m. ET, to discuss key data presentations at ASH, including data from the Phase 3 inMIND study presented during the late breaking session and its BET inhibitor program.

To access the conference call, please dial 877-407-3042 for domestic callers or 201-389-0864 for international callers. When prompted, provide the conference identification number, 13750244.

If you are unable to participate, a replay of the conference call will be available for thirty days. The replay dial-in number for the United States is 877-660-6853 and the dial-in number for international callers is 201-612-7415. To access the replay, you will need the conference identification number, 13750244.

The live webcast with slides can be accessed at Investor.Incyte.com and will be available for replay for ninety days.

About Jakafi® (ruxolitinib)
Jakafi® (ruxolitinib) is a JAK1/JAK2 inhibitor approved by the U.S. FDA for treatment of polycythemia vera (PV) in adults who have had an inadequate response to or are intolerant of hydroxyurea; intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF in adults; steroid-refractory acute GVHD in adult and pediatric patients 12 years and older; and chronic GVHD after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older.

Jakafi is a registered trademark of Incyte.

About Monjuvi® (tafasitamab-cxix)
Monjuvi® (tafasitamab-cxix) 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 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 diffuse large B-cell lymphoma (DLBCL) who are not eligible for autologous stem cell transplant (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 Zynyz® (retifanlimab-dlwr)

Zynyz® (retifanlimab-dlwr), is an intravenous PD-1 inhibitor indicated in the U.S. for the treatment of adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC). This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Zynyz is marketed by Incyte in the U.S. In 2017, Incyte entered into an exclusive collaboration and license agreement with MacroGenics, Inc. for global rights to retifanlimab.

Zynyz is a registered trademark of Incyte.

About Pemazyre® (pemigatinib)

Pemazyre® (pemigatinib) is a kinase inhibitor indicated in the United States for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test*. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Pemazyre is also the first targeted treatment approved for use in the United States for treatment of adults with relapsed or refractory myeloid/lymphoid neoplasms (MLNs) with FGFR1 rearrangement.

In Japan, Pemazyre is approved for the treatment of patients with unresectable biliary tract cancer (BTC) with a fibroblast growth factor receptor 2 (FGFR2) fusion gene, worsening after cancer chemotherapy.

In Europe, Pemazyre is approved for the treatment of adults with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy.

Pemazyre is a potent, selective, oral inhibitor of FGFR isoforms 1, 2 and 3 which, in preclinical studies, has demonstrated selective pharmacologic activity against cancer cells with FGFR alterations.

Pemazyre is marketed by Incyte in the United States, Europe and Japan.

Pemazyre and the Pemazyre logo are registered trademarks of Incyte.

* Pemazyre® (pemigatinib) [Package Insert]. Wilmington, DE: Incyte; 2020.

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 Niktimvo from UCB. In September 2021, Syndax and Incyte entered into an exclusive worldwide co-development and co-commercialization license agreement for Niktimvo 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.
All other trademarks are the property of their respective owners.
Niktimvo (axatilimab-csfr) is licensed from Syndax.

About Iclusig® (ponatinib) tablets

Iclusig® (ponatinib) targets not only native BCR-ABL but also its isoforms that carry mutations that confer resistance to treatment, including the T315I mutation, which has been associated with resistance to other approved TKIs.

In the EU, Iclusig is approved for the treatment of adult patients with chronic phase, accelerated phase or blast phase chronic myeloid leukemia (CML) who are resistant to dasatinib or nilotinib; who are intolerant to dasatinib or nilotinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation, or the treatment of adult patients with Philadelphia-chromosome positive acute lymphoblastic leukemia (Ph+ ALL) who are resistant to dasatinib; who are intolerant to dasatinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation.

Click here to view the Iclusig EU Summary of Medicinal Product Characteristics.

Incyte has an exclusive license from Takeda Pharmaceuticals International AG to commercialize ponatinib in the European Union and 29 other countries, including Switzerland, UK, Norway, Turkey, Israel and Russia. Iclusig is marketed in the U.S. by Millennium Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda Pharmaceutical Company Limited.

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, the potential presented by that pipeline, 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 the 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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Media
media@incyte.com

Investors
ir@incyte.com

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