Incyte to Spotlight More Than 40 Hematology and Oncology Abstracts Including a Plenary Presentation at the ASH Annual Meeting

November 2, 2023

– Sixteen oral presentations, as well as a plenary session and poster presentations, highlight new advances across eight of the Company's medicines

– Plenary Scientific Session will feature the full data from AGAVE-201 evaluating axatilimab, an anti-CSFR-1R monoclonal antibody, in patients with chronic graft-versus-host disease (GVHD)

– Incyte to host an in-person analyst and investor event on Monday, December 11, 2023 from 12:00-1:30 p.m. PT to discuss key data presentations at ASH

WILMINGTON, Del.--(BUSINESS WIRE)--Nov. 2, 2023-- Incyte (Nasdaq:INCY) today announced that more than 40 abstracts highlighting data from eight of its hematology and oncology products will be presented at the upcoming 65th American Society of Hematology Annual Meeting 2023 (ASH 2023), held December 9-12, 2023, in San Diego and virtually.

"We have continued to make significant progress in advancing our hematology and oncology pipeline with the goal to deliver better medicines for a range of diseases that have limited treatment options, including myeloproliferative neoplasms (MPNs) and chronic graft-versus-host disease (GVHD)," said Pablo J. Cagnoni, M.D., President and Head of Research and Development, Incyte. "We are excited to showcase the depth of our portfolio and clinical progress at this year's ASH congress. In particular, we look forward to the presentation of the axatilimab AGAVE-201 trial results in patients with chronic GVHD at the Plenary Scientific Session, as well as the numerous oral and poster presentations including new data for our mutant CALR, BET, ALK2 and CK0804 programs in MPNs. Additionally, we are proud that the first presentation of data for INCB160058, our new potentially disease modifying JAK2V617F therapy for patients with MPNs, will be at this year's meeting."

Select key abstract presentations from Incyte-developed and partnered programs include:

Plenary Scientific Session

Axatilimab

Safety and Efficacy of Axatilimab at 3 Different Doses in Patients with Chronic Graft-Versus-Host Disease (AGAVE-201)[1] (Abstract #1. Plenary Scientific Session. Sunday, December 10, 5:00 p.m. – 7:00 p.m. ET)

Oral Presentations

Ruxolitinib (MPN)

A Real-World Evaluation of Risk Factors for Disease Progression in Patients with Polycythemia Vera (PV) Enrolled in REVEAL (Abstract #385. Session: 906. Outcomes Research – Myeloid Malignancies: Risk Factors and Health Disparities. Saturday, December 9, 7:00 p.m. ET)

Phase 1/2 Study of the Activin Receptor-Like Kinase-2 Inhibitor Zilurgisertib (INCB000928, LIMBER-104) as Monotherapy or with Ruxolitinib in Patients with Anemia Due to Myelofibrosis (Abstract #624. Session: 634. Myeloproliferative Syndromes: Clinical and Epidemiological: Charting The Future Of MPN Therapies. Sunday, December 10, 8:45 p.m. ET)

Bromodomain and Extra-Terminal (BET) Inhibitor INCB057643 (LIMBER-103) in Patients with Relapsed or Refractory Myelofibrosis (R/R MF) and Other Advanced Myeloid Neoplasms: A Phase 1 Study (Abstract #750. Session: 634. Myeloproliferative Syndromes: Clinical and Epidemiological: Treatment and Outcomes in MPNs. Monday, December 11, 2:45 p.m. ET)

Ruxolitinib (GVHD)

Ruxolitinib in Patients with Chronic Graft-Versus-Host Disease: Three-Year Final Analysis of Efficacy and Safety of the Phase 3 REACH3 Study[2] (Abstract #654. Session: 722. Allogeneic Transplantation: Acute and Chronic GVHD, Immune Reconstitution: Innovative Approaches to GVHD Prevention and Treatment. Sunday, December 10, 8:45 p.m. ET)

Tafasitamab

Tafasitamab for the Treatment of Relapsed/Refractory (R/R) Diffuse Large B-cell Lymphoma (DLBCL) in the U.S. Real-World Setting (Abstract #265. Session: 905. Outcomes Research – Lymphoid Malignancies: Outcomes Research in Lymphoma/CLL: Biomarkers, Dosing Strategies, and Big-Data. Saturday, December 9, 5:00 p.m. ET)

Itacitinib

Itacitinib for the Prevention of Immune Effector Cell Therapy-Associated Cytokine Release Syndrome: Results from the Phase 2 INCB 39110-211 Placebo-Controlled, Randomized Cohort (Abstract #356. Session: 705. Cellular Immunotherapies: Late Phase and Commercially Available Therapies: Prediction and Management of CAR-T Cell Related Toxicity. Saturday, December 9, 7:15 p.m. ET)

INCB160058

Preclinical Evaluation of INCB160058 – A Novel and Potentially Disease-Modifying Therapy for JAK2V617F Mutant Myeloproliferative Neoplasms (Abstract #860. Session: 631. Myeloproliferative Syndromes and Chronic Myeloid Leukemia: Basic and Translational: Lineage Tracing

and Novel Target Discovery. Monday, December 11, 6:00 p.m. ET)

Poster Presentations

Ruxolitinib (MPN)

Effect of New or Worsening Anemia on Clinical Outcomes in 2,233 Patients with Myelofibrosis (MF) Treated with Ruxolitinib in the Expanded-Access JUMP Study (Abstract #5174. Session: 906. Outcomes Research—Myeloid Malignancies: Poster IIIMonday, December 11, 9:00 p.m. – 11:00 p.m. ET)

Ruxolitinib Treatment in Polycythemia Vera Results in Reduction in JAK2 Allele Burden in Addition to Improvement in Hematocrit Control and Symptom Burden (Abstract #4553. Session: 634. Myeloproliferative Syndromes: Clinical and Epidemiological: Poster III. Monday, December 11, 9:00 p.m. – 11:00 p.m. ET)

High Rate of Disease Progression in Patients with Low-Risk Myelofibrosis (MF) Enrolled in the Prospective, Real-World, MOST Study Abstract #3803. Session: 906. Outcomes Research—Myeloid Malignancies: Poster IISunday, December 10, 9:00 p.m. – 11:00 p.m. ET)

Progression to Myelofibrosis in Patients with Essential Thrombocythemia: A Real-World Analysis from the Prospective MOST Study (Abstract #2433. Session: 906. Outcomes Research—Myeloid Malignancies: Poster ISaturday, December 9, 8:30 p.m. – 10:30 p.m. ET)

Clinical and Disease Characteristics of Patients With Myelofibrosis and Essential Thrombocythemia that Harbor a Calreticulin (CALR) Gene Mutation: Subanalysis of the MOST Study (Abstract #3812. Session: 906. Outcomes Research—Myeloid Malignancies: Poster IISunday, December 10, 9:00 p.m. – 11:00 p.m. ET)

Comparison of the Enzymatic and Cellular Profiles of Clinical JAK2 Inhibitors for the Treatment of Myelofibrosis (Abstract #4532. Session: 631. Myeloproliferative Syndromes and Chronic Myeloid Leukemia: Basic and Translational: Poster III. Monday, December 11, 9:00 p.m. – 11:00 p.m. ET)

ALK2 and JAK2 Inhibition for Improved Treatment of Anemia in Myelofibrosis Patients: Preclinical Profile of an ALK2 Inhibitor Zilurgisertib in Combination with Ruxolitinib (Abstract #1789. Session: 631. Myeloproliferative Syndromes and Chronic Myeloid Leukemia: Basic and Translational: Poster I. Saturday, December 9, 8:30 p.m. – 10:30 p.m. ET)

The Association between Blood Cell Counts and Thrombotic Events in Japanese Patients with Polycythemia Vera: A Retrospective Database Study[2] (Abstract #3191. Session: 634. Myeloproliferative Syndromes: Clinical and Epidemiological: Poster II. Sunday, December 10, 9:00 p.m. – 11:00 p.m. ET)

Tafasitamab

Real-World Use of Tafasitamab (tafa) for Relapsed or Refractory (R/R) Diffuse Large B-cell Lymphoma (DLBCL) Among Racial and Ethnic Minorities in the United States (Abstract #2415. Session: 905. Outcomes Research – Lymphoid Malignancies: Poster I. Saturday, December 9, 8:30 – 10:30 p.m. ET)

Tafasitamab in Combination with a CD20xCD3 Bispecific T-cell Engager Significantly Prolongs Survival in Preclinical Lymphoma Models[3] (Abstract #2813. Session: 605. Molecular Pharmacology and Drug Resistance: Lymphoid Neoplasms: Poster II. Sunday, December 10, 9:00 – 11:00 p.m. ET)

Pemigatinib

Deep and Durable Cytogenetic and Molecular Responses with Pemigatinib in Myeloid/Lymphoid Neoplasms with Fibroblast Growth Factor Receptor 1 Rearrangement: The FIGHT-203 Study (Abstract #4551. Session: 634. Myeloproliferative Syndromes: Clinical and Epidemiological: Poster III. Monday, December 11, 9:00 p.m. – 11:00 p.m. ET)

Ponatinib

Long-term Results From the OPTIC Trial: A Dose-Optimization Study of 3 Starting Doses of Ponatinib[4] (Abstract #3164. Session: 632. Chronic Myeloid Leukemia: Clinical and Epidemiological: Poster II. Sunday, December 10, 9:00 – 11:00 p.m. ET)

Ponatinib Versus Imatinib in Patients with Newly Diagnosed Ph+ ALL: Subgroup Analysis of the Phase 3 PhALLCON Study[4] (Abstract #2871. 614. Acute Lymphoblastic Leukemias: Therapies, Excluding Transplantation and Cellular Immunotherapies: Poster II. Sunday, December 10, 9:00 – 11:00 p.m. ET)

Itacitinib

Janus Kinase (JAK) 1 Inhibition Results in Significant Changes in Serum Proteins and Peripheral T-Cell Populations that Correlated with Clinical Scores in Chronic Graft-Versus-Host Disease (GVHD) Patients (an Analysis from GRAVITAS-309) (Abstract #2197. Session: 722. Allogeneic Transplantation: Acute and Chronic GVHD, Immune Reconstitution: Poster I. Saturday, December 9, 8:30 – 10:30 p.m. ET)

CK0804

A Phase 1b, Open-Label Study of Add on Therapy with CK0804 in Participants with Myelofibrosis and Suboptimal Response to Ruxolitinib[5] (Abstract #1813. Session: 634. Myeloproliferative Syndromes: Clinical and Epidemiological: Poster I. Saturday, December 9, 8:30 – 10:30 p.m. ET)

More information regarding the congress is available on the ASH website: https://www.hematology.org/meetings/annual-meeting. This in-person event will be broadcast virtually and access to the meeting's virtual platform is included with registration.

Conference Call and Webcast

Incyte will host an in-person analyst and investor event on Monday, December 11, 2023, from 12:00-1:30 p.m. PT (3:00–4:30 p.m. ET) to discuss the key data presentations at ASH. The event will be webcasted and can be accessed via the Events and Presentations tab of the Investor section of Incyte.com and it will be available for replay for 30 days.

Conference call details will be provided on our website.

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 graft-versus-host disease (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[6].

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.

About Iclusig® (ponatinib) tablets

Ponatinib (Iclusig®) 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 Monjuvi®/Minjuvi® (tafasitamab)

Monjuvi®/Minjuvi® (tafasitamab) is a humanized Fc-modified CD19 targeting immunotherapy. 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).

In the United States, Monjuvi® (tafasitamab-cxix) is approved 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). This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). Please see the U.S. full Prescribing Information for Monjuvi for important safety information.

In Europe, Minjuvi® (tafasitamab) received conditional marketing authorization 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.

Tafasitamab is being clinically investigated as a therapeutic option in B-cell malignancies in several ongoing combination trials. Its safety and efficacy for these investigational uses have not been established in pivotal trials.

Monjuvi® and Minjuvi® are registered trademarks of MorphoSys AG. Tafasitamab is co-marketed by Incyte and MorphoSys under the brand name Monjuvi® in the U.S., and marketed by Incyte under the brand name Minjuvi® in Europe and Canada.

XmAb® is a registered trademark of Xencor, Inc.

About Pemazyre® (pemigatinib)

Pemazyre 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[7]. 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 is a trademark of Incyte Corporation.

About Axatilimab
Axatilimab is an investigational monoclonal antibody that targets colony stimulating factor-1 receptor, or CSF-1R, a cell surface protein thought to control the survival and function of monocytes and macrophages. In pre-clinical models, inhibition of signaling through the CSF-1 receptor has been shown to reduce the number of disease-mediating macrophages along with their monocyte precursors, which has been shown to play a key role in the fibrotic disease process underlying diseases such as chronic graft-versus-host disease (GVHD) and idiopathic pulmonary fibrosis (IPF). Phase 1/2 data of axatilimab in chronic GVHD demonstrating its broad activity and tolerability was last presented at the 63rd American Society of Hematology Annual Meeting. Axatilimab was granted Orphan Drug Designation by the U.S. Food and Drug Administration for the treatment of patients with chronic GVHD and IPF. In September 2021, Syndax and Incyte entered into an exclusive worldwide co-development and co-commercialization license agreement for axatilimab. Axatilimab is being developed under an exclusive worldwide license from UCB entered into between Syndax and UCB in 2016.

Enrollment in the Company's global pivotal Phase 2 AGAVE-201 Phase 2 study evaluating the efficacy, safety, and tolerability of axatilimab in patients with recurrent or refractory active chronic GVHD who have received at least two prior lines of systemic therapy is complete, and topline data is expected mid-2023. Additionally, a Phase 1 combination trial of ruxolitinib and axatilimab, led by Incyte, is in preparation and expected to initiate by end of the first quarter of 2023, and a Phase 2b trial of axatilimab in patients with idiopathic pulmonary fibrosis led by Syndax is expected to begin in the fourth quarter of 2022.

For more information about AGAVE-201, please visit https://www.clinicaltrials.gov/study/NCT04710576.

About Itacitinib
Itacitinib (INCB039110) is a novel and selective JAK1 inhibitor currently in clinical studies for the first-line treatment of patients with acute and chronic graft-versus-host disease (GVHD).

Itacitinib was discovered at Incyte, and Incyte holds the global development and commercialization rights for itacitinib with the exception of China, where the rights to develop and commercialize itacitinib have been licensed to Innovent Biologics, Inc.

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 Incyte's clinical development 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 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: 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, EMA, and other regulatory authorities; the efficacy or safety of Incyte and its partners' products; the acceptance of Incyte and its partners' products in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; and other risks detailed from time to time in Incyte's reports filed with the Securities and Exchange Commission, including its annual report and its quarterly report on Form 10-Q for the quarter ended September 30, 2023. Incyte disclaims any intent or obligation to update these forward-looking statements.

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[1] Syndax-sponsored abstract
[2] Novartis-sponsored abstract
[3] MorphoSys-sponsored abstract
[4] Takeda-sponsored abstract
[5] Cellenkos-sponsored abstract
[6] Jakafi (ruxolitinib) tablets: Prescribing Information. U.S. Food and Drug Administration.
[7] Pemazyre (pemigatinib): Prescribing Information. U.S. Food and Drug Administration.

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Media
media@incyte.com

Investors
ir@incyte.com

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