Incyte Announces More than 50 Abstracts Accepted for Presentation at the 2025 ASH Annual Meeting

November 3, 2025

- *INCA033989, a first-in-class mutant calreticulin (mutCALR)-targeted monoclonal antibody, will be showcased in three presentations, including new Phase 1 monotherapy and combination data in myelofibrosis (MF), updated data in essential thrombocythemia (ET) and translational data demonstrating disease modifying activity in both ET and MF.*

- *Additionally, the more than 50 abstracts accepted at ASH include new and updated data from Incyte's MPN, GVHD and hematology programs including interim safety data evaluating axatilimab (Niktimvo™) in combination with ruxolitinib in GVHD*

- *Incyte to host an investor event and webcast highlighting the mutCALR data from the oral presentation at ASH on Sunday, December 7, 2025, from 11:00 a.m.-12:30 p.m. ET*

WILMINGTON, Del.--(BUSINESS WIRE)--Incyte (Nasdaq:INCY) today announced that data from key programs in its oncology portfolio will be presented in both oral and poster sessions at the 2025 American Society of Hematology (ASH) Annual Meeting, to be held December 6 – 9, 2025, in Orlando.

"This year's Incyte presentations highlight the potential of our portfolio to transform the treatment of blood cancers, specifically for patients with myeloproliferative neoplasms (MPNs)," said Pablo J. Cagnoni, M.D., President and Head of Research and Development, Incyte. "New data for our first-in-class mutCALR-targeted monoclonal antibody, INCA033989, as a monotherapy in patients with myelofibrosis (MF) who are intolerant or refractory to ruxolitinib, and in combination with ruxolitinib in patients with MF who experience a suboptimal response to ruxolitinib monotherapy will be highlighted as an oral presentation. Updated data for INCA033989 in essential thrombocythemia (ET) will also be presented. Additionally, we look forward to sharing the results from axatilimab in graft-versus-host disease (GVHD) and tafasitamab in follicular lymphoma (FL) – all of which showcase the progress and promise of our oncology portfolio."

Details on Incyte data presentations at ASH include:

Oral Presentations

INCA033989 (mutCALR)

Molecular Characterization Of Patients (Pts) With Myeloproliferative Neoplasms Treated With INCA033989 Demonstrates Selective Targeting Of *CALR* Mutant Hematopoietic Cells
(Session Title: 631. Myeloproliferative Syndromes and Chronic Myeloid Leukemia: Basic and Translational: Precision Targeting in MPN. [December 6, 9:30 – 11:00 a.m. ET]. Publication #71.)

Safety And Efficacy Of The Mutant Calreticulin-Specific Monoclonal Antibody INCA033989 As Monotherapy Or In Combination With Ruxolitinib In Patients (Pts) With Myelofibrosis (MF): Preliminary Results From Dose Escalation Of Two Global Phase 1 Studies
(Session Title: 634. Myeloproliferative Syndromes: Clinical and Epidemiological: Between a Rock and a Ropeg - Innovative Therapies for MPNs. [December 7, 9:30 – 11:00 a.m. ET]. Publication #484.)

Safety And Efficacy Of INCA033989, A Novel First In Class Mutant Calreticulin-Specific Monoclonal Antibody, In Patients With Essential Thrombocythemia
(Session Title: 634. Myeloproliferative Syndromes: Clinical and Epidemiological: Drivers and Mast Cells and Blasts, Oh My! - Insights and Treatments for MPNs and Mastocytosis. [December 8, 4:30 – 6:00 p.m. ET]. Publication #1024.)

Axatilimab (Niktimvo®)

Safety And Feasibility Of 0.6 mg/kg Every 4 Weeks Dosing Of Axatilimab In Patients Treated In The AGAVE-201 Study
(Session Title: 722. Allogeneic Transplantation: Acute and Chronic GVHD and Immune Reconstitution: Acute and Chronic GVHD and Immune Reconstitution. [December 6, 2:00 – 3:30 p.m. ET]. Publication #272.)

INCB057643 (BET)

Safety And Efficacy Of Bromodomain And Extra-Terminal Protein Inhibitor INCB057643 Monotherapy In Patients With Relapsed Or Refractory Myelofibrosis And Other Advanced Myeloid Neoplasms: A Phase 1 Study
(Session Title: 634. Myeloproliferative Syndromes: Clinical and Epidemiological: Beyond JAK Inhibition - Therapeutic Innovation and Transplant Strategies in Myelofibrosis. [December 8, 2:45 – 3:00 p.m. ET]. Publication #907)

Ruxolitinib (Jakafi®)

Risk Factors For Progressive Kidney Impairment Among Patients With Polycythemia Vera (PV) Are Recapitulated And Treatable In Mouse Models Of PV
(Session Title: 908. Outcomes Research: Myeloid Malignancies: Treatment and Outcomes in the Real-World. [December 7, 12:00 – 1:30 p.m. ET].

Publication #605.)

Poster Presentations

Axatilimab (Niktimvo®)

Pharmacodynamic Analysis Of AGAVE-201 Indicates Changes In CSF-1R–Expressing Cells And Associated Biomarkers Potentially Contributing To Chronic Graft-Versus-Host Disease Resolution
(Session Title: 722. Allogeneic Transplantation: Acute and Chronic GVHD and Immune Reconstitution: Poster I. [December 6, 5:30 – 7:30 p.m. ET]. Publication #2458.)

Trial In Progress: A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Of Axatilimab And Corticosteroids As Initial Treatment For Moderate To Severe Chronic Graft-Versus-Host Disease
(Session Title: 722. Allogeneic Transplantation: Acute and Chronic GVHD and Immune Reconstitution: Poster II. [December 7, 6:00 – 8:00 p.m. ET]. Publication #4256.)

Long-Term Treatment Duration And Safety Of Axatilimab Among Patients With Chronic Graft-Versus-Host Disease In AGAVE-201
(Session Title: 722. Allogeneic Transplantation: Acute and Chronic GVHD and Immune Reconstitution: Poster III. [December 8, 6:00 – 8:00 p.m. ET]. Publication #6010.)

Safety Analysis Of Axatilimab In Patients With Chronic Graft-Versus-Host Disease In An Expanded Access Program
(Session Title: 722. Allogeneic Transplantation: Acute and Chronic GVHD and Immune Reconstitution: Poster III. [December 8, 6:00 – 8:00 p.m. ET]. Publication #6008.)

Axatilimab In Combination With Ruxolitinib In Patients With Newly Diagnosed Chronic Graft-Versus-Host Disease: Interim Safety Analysis Of A Randomized, Phase 2 Study
(Session Title: 722. Allogeneic Transplantation: Acute and Chronic GVHD and Immune Reconstitution: Poster III. [December 8, 6:00 – 8:00 p.m. ET]. Publication #6012.)

INCB000928 (ALK2)

The Activin Receptor-Like Kinase-2 Inhibitor Zilurgisertib (INCB000928) As Monotherapy Or With Ruxolitinib In Patients With Anemia Due To Myelofibrosis: Phase 1/2 Study Final Results
(Session Title: 634. Myeloproliferative Syndromes: Clinical and Epidemiological: Poster II. [December 7, 6:00 – 8:00 p.m. ET]. Publication #3795.)

INCB057643 (BET)

INCB057643, A Bromodomain And Extra-Terminal Protein Inhibitor, In Combination With Ruxolitinib In Patients With Myelofibrosis: A Phase 1 Study Of Safety And Efficacy
(Session Title: 634. Myeloproliferative Syndromes: Clinical and Epidemiological: Poster III. [December 8, 6:00 – 8:00 p.m. ET]. Publication #5574.)

INCB160058 (JAK2V617F)

INCB160058 Selectively Targets JAK2V617F-Driven Hematopoiesis In Diverse And Drug-Resistant Models Of Myeloproliferative Neoplasms
(Session Title: 604. Molecular Pharmacology and Drug Resistance: Myeloid Neoplasms: Poster II. [December 7. 6:00 – 8:00 p.m. ET]. Publication #3275.)

A Multicenter, Open-Label Phase 1 Study Of INCB160058, A First-In-Class JAK2V617F Mutant–Selective Inhibitor, In Patients With Myelofibrosis, Polycythemia Vera, Or Essential Thrombocythemia
(Session Title: 634. Myeloproliferative Syndromes: Clinical and Epidemiological: Poster I. [December 6, 5:30 – 7:30 p.m. ET]. Publication #2051.)

Ruxolitinib (Jakafi®)

Impact Of Ruxolitinib On Corticosteroid Treatment Patterns In 1147 Patients With Chronic Graft-Versus-Host Disease In Real-World Practice In The United States: A Long-Term Follow-Up Analysis
(Session Title: 722. Allogeneic Transplantation: Acute and Chronic GVHD and Immune Reconstitution: Poster I. [December 6, 5:30 – 7:30 p.m. ET]. Publication #2452.)

Clinical And Disease Characteristics Of Initial Participants At Time Of Enrollment In THRIVE, A Prospective, Observational Cohort Study Of Patients At Risk For Chronic Graft-Versus-Host Disease
(Session Title: 722. Allogeneic Transplantation: Acute and Chronic GVHD and Immune Reconstitution: Poster I. [December 6, 5:30 – 7:30 p.m. ET]. Publication #2446.)

Ruxolitinib Duration Of Treatment And Effect On Phlebotomy Use Among 2369 Patients With Polycythemia Vera: A Real-World Analysis Of The Medicare Fee-For-Service Claims Database
(Session Title: 908. Outcomes Research: Myeloid Malignancies: Poster I. [December 6, 5:30 – 7:30 p.m. ET]. Publication #2826.)

Longitudinal Genomic Shifts Associated With Disease Transformation In Patients With Polycythemia Vera (PV) Enrolled In REVEAL
(Session Title: 631. Myeloproliferative Syndromes and Chronic Myeloid Leukemia: Basic and Translational: Poster II. [December 7, 6:00 – 8:00 p.m. ET]. Publication #3749.)

Identification Of Biomarkers To Predict Disease Progression Via Molecular Analysis Of Patients (Pts) With Low-Risk Myelofibrosis (MF) Enrolled In The MOST Study
(Session Title: 631. Myeloproliferative Syndromes and Chronic Myeloid Leukemia: Basic and Translational: Poster III. [December 8, 6:00 – 8:00 p.m. ET]. Publication #5526.)

Real-World Treatment Duration Of Ruxolitinib And Use Of Transfusion Among 2268 Patients With Myelofibrosis: An Analysis Of The

Medicare Fee-For-Service Claims Database
(Session Title: 908. Outcomes Research: Myeloid Malignancies: Poster III. [December 8, 6:00 – 8:00 p.m. ET]. Publication #6391.)

Ruxolitinib XR

Bioequivalence Of Ruxolitinib Once-Daily Extended-Release Vs Twice-Daily Immediate-Release Tablets In Healthy Adults
(Session Title: 604. Molecular Pharmacology and Drug Resistance: Myeloid Neoplasms: Poster III. [December 8, 6:00 – 8:00 p.m. ET]. Publication #5045.)

Tafasitamab (Monjuvi®)

Phase 3 Study (inMIND) Of Tafasitamab Plus Lenalidomide And Rituximab For Relapsed Or Refractory Follicular Lymphoma: Clinical Characteristics And Outcomes By Age
(Session Title: 623. Mantle Cell, Follicular, Waldenstrom's, and Other Indolent B Cell Lymphomas: Clinical and Epidemiological: Poster II. [December 7, 6:00 – 8:00 p.m. ET]. Publication #3582.)

Phase 3 Study (inMIND) Of Tafasitamab Plus Lenalidomide And Rituximab For Relapsed Or Refractory Follicular Lymphoma: Clinical Characteristics And Outcomes Of Patients Receiving Second-Line Treatment
(Session Title: 623. Mantle Cell, Follicular, Waldenstrom's, and Other Indolent B Cell Lymphomas: Clinical and Epidemiological: Poster I. [December 6, 5:30 – 7:30 p.m. ET]. Publication #1819.)

CD19 Expression Is Preserved Following CD19-Directed Monoclonal Antibody Therapy With Tafasitamab
(Session Title: 629. Aggressive Lymphomas, Immunotherapy Including Bispecific Antibodies: Poster III. [December 8, 6:00 – 8:00 p.m. ET]. Publication #5515.)

Phase 3 Study (inMIND) Of Tafasitamab Plus Lenalidomide And Rituximab For Relapsed Or Refractory Follicular Lymphoma: Clinical Characteristics And Outcomes Of High-Risk Patients
(Session Title: 623. Mantle Cell, Follicular, Waldenstrom's, and Other Indolent B Cell Lymphomas: Clinical and Epidemiological: Poster III. [December 8, 6:00 – 8:00 p.m. ET]. Publication #5367.)

All regular abstracts accepted for presentation at the ASH Annual Meeting 2025 are available online via the ASH website. More information regarding the 2025 ASH Congress can be found at: https://www.hematology.org/meetings/annual-meeting/schedule-and-program/programs.

Conference Call and Webcast
Incyte will host an investor event and webcast on Sunday, December 7, 2025, from 11:00 a.m.-12:30 p.m. ET to discuss key mutCALR data being presented 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.

About Myeloproliferative Neoplasms
Myeloproliferative neoplasms (MPNs) are a closely related group of blood cancers in which the bone marrow functions abnormally. The bone marrow is where the body's blood cells are made. MPNs are progressive blood cancers that can strike anyone at any age, but they are more common in older adults. Estimates of the prevalence of MPNs vary, but analysis of claims data suggests there may be as many as 200,000 people in the U.S. living with the most prevalent MPNs: myelofibrosis, polycythemia vera or essential thrombocythemia (ET).1

About Mutations in Calreticulin (mutCALR)
Calreticulin (CALR) is a protein involved in the regulation of cellular calcium levels and normal protein folding. Somatic, or non-inherited, DNA mutations in the CALR gene (mutCALR) can result in abnormal protein function and lead to the development of myeloproliferative neoplasms (MPNs),2 a closely related group of clonal blood cancers in which the bone marrow functions abnormally, overproducing blood cells.3,4 Among two types of MPNs, essential thrombocythemia (ET) and myelofibrosis (MF), mutCALR drives 25-35% of all cases.2,3 There are approximately 60,000 patients in the U.S. and Europe with mutCALR positive ET.5

Incyte is at the forefront of developing novel therapies for patients with mutCALR ET or MF that target only malignant cells, sparing normal cells, including INCA033989, a first-in-class, mutCALR-specific therapy.

About the INCA033989 Clinical Trial Program
The clinical trial program for INCA033989 includes two multicenter, open-label Phase 1 studies, INCA33989-101 (NCT05936359) and INCA33989-102 (NCT06034002), enrolling ~225 patients outside of the U.S. and ~140 patients in the U.S., respectively. The studies are evaluating the safety, tolerability, dose-limiting toxicity (DLT) and maximum tolerated dose (MTD) and/or recommended dose(s) for expansion (RDE) of INCA033989 administered as a monotherapy or in combination with ruxolitinib in patients with myeloproliferative neoplasms (MPNs), including essential thrombocythemia (ET) and myelofibrosis (MF). The intent of Part 1A (dose escalation) is to identify the MTD and/or the RDE of INCA033989 among patients with MF and ET. In Part 1A INCA033989 is administered intravenously every two weeks at a protocol defined dose ranging from 24 mg. to 2,500 mg. In Part 1B (dose expansion), INCA033989 is administered at the RDE(s) identified during Part 1A.

The primary endpoint of the studies focuses on safety and tolerability as measured by: the number of participants with DLTs up to 28 days, the number of participants with treatment-emergent adverse events (TEAEs) up to 3 years and 60 days, and the number of participants with TEAEs leading to dose modification or discontinuation up to 3 years and 60 days. Secondary endpoints include response rates, mean change of ET total symptom score from baseline, percentage of MF patients achieving spleen volume reduction, MF patient anemia response, mean change in disease-related allele burden and various pharmacokinetics measures up to 3 years and 60 days.

For more information on the study, please visit: https://clinicaltrials.gov/study/NCT05936359 and https://clinicaltrials.gov/study/NCT06034002.

About Niktimvo™ (axatilimab-csfr)
Niktimvo (axatilimab-csfr) is a first-in-class colony stimulating factor-1 receptor (CSF-1R)-blocking antibody approved for use in the U.S. for the treatment of chronic graft-versus-host disease (GVHD) 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 chronic GVHD 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 (NCT06585774) are underway. 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.

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. 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). Incyte licenses exclusive worldwide rights to develop and commercialize tafasitamab from Xencor, Inc.

In the U.S., Monjuvi is approved by the U.S. Food and Drug Administration in combination with lenalidomide and rituximab for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL).

Monjuvi is not indicated and is not recommended for the treatment of patients with relapsed or refractory marginal zone lymphoma outside of controlled clinical trials.

Additionally, Monjuvi received accelerated approval in the United States 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 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 progress and promise of Incyte’s oncology portfolio, 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 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, 2025. Incyte disclaims any intent or obligation to update these forward-looking statements.

1 Data on file

2 Raghavan, M., Wijeyesakere S.J., Peters L.R., Del Cid N. (2013) Calreticulin in the immune system: ins and outs. *Trends in Immunology*, 34(1):13-21. Link to source (https://www.cell.com/trends/immunology/abstract/S1471-4906(12)00131-7?_returnURL=https%3A%2F%2Flinkinghub.elsevier.com%2Fretrieve%2Fpii%2FS1471490612001317%3Fshowall%3Dtrue)

3 Nangalia J. Massie C.E., Baxter E.J., Nice F.L., et al. (2013) Somatic CALR mutations in myeloproliferative neoplasms with nonmutated JAK2. *New England Journal of Medicine*,369(25):2391-2405. Link to source (https://www.nejm.org/doi/10.1056/NEJMoa1312542?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200www.ncbi.nlm.nih.gov)

4 Klampfl T., Gisslinger, H., Harutyunyan A.S., et al. (2013) Somatic mutations of calreticulin in myeloproliferative neoplasms. *New England Journal of Medicine*, 369(25):2379-2390. Link to source (https://www.nejm.org/doi/10.1056/NEJMoa1311347?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200www.ncbi.nlm.nih.gov)

5 Epidemiology Source: DRG, Prevalence 2026.

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