Incyte Announces Multiple Presentations, Including New Late-Breaking Data for its mutCALR-Directed Monoclonal Antibody (INCA033989), Accepted for Presentation at EHA 2025

June 3, 2025

- *Late-breaking oral presentation will highlight new data from a trial of INCA033989, an anti-mutant calreticulin (mutCALR)-directed monoclonal antibody, in patients with essential thrombocythemia (ET)*
- *Incyte to host an in-person analyst and investor event highlighting the mutCALR data at EHA on Sunday, June 15, 2025, from 6:00 - 7:30 a.m. EDT (12:00 - 1:30 p.m. CEST)*

WILMINGTON, Del.--(BUSINESS WIRE)--Jun. 3, 2025-- Incyte (Nasdaq:INCY) today announced that data from numerous programs in its hematology/oncology portfolio will be presented at the 2025 European Hematology Association (EHA) congress, held June 12 – 15, 2025, in Milan.

"We're looking forward to presenting new data from across our hematology/oncology portfolio at the 2025 EHA Congress, including late-breaking data for our first in class, mutCALR-directed monoclonal antibody, INCA033989," said Pablo J. Cagnoni, M.D., President and Head of Research and Development, Incyte. "We believe the data that will be presented at the late-breaking session demonstrate the impact of the novel mechanism of action of this monoclonal antibody against mutCALR-driven essential thrombocythemia (ET), and support its potential to be a disease modifying agent and thus transform the treatment of patients with myeloproliferative neoplasms (MPNs) like essential thrombocythemia (ET)."

Key Incyte abstracts accepted for presentation at EHA include:

Late-Breaking Oral Presentation

INCA033989 (mutCALR)

INCA33989 is a Novel, First in Class, Mutant Calreticulin-Specific Monoclonal Antibody That Demonstrates Safety and Efficacy in Patients with Essential Thrombocythemia (ET)
(Session Title: Late-Breaking Oral Session. June 15, 3:15 – 4:45 a.m. EDT [9:15-10:45 a.m. CEST]. Abstract #LB4002.)

Oral Presentations

INCA035784 (mutCALR)

INCA035784, a Novel, Equipotent T Cell Redirecting Antibody for Patients with Myeloproliferative Neoplasms Carrying Different Types of Calreticulin Mutations
(Session Title: Novel and Experimental Approaches to Study and Treat MPN. June 15, 5:30 – 5:45 a.m. EDT [11:30 – 11:45 a.m. CEST]. Abstract #S212.)

Ruxolitinib

Clinical Outcomes in Patients with Myelofibrosis Treated with Ruxolitinib and Anemia Supporting Medications
(Session Title: Assessment of Risk and Survival in MPN. June 13, 11:45 a.m. – 12:00 p.m. EDT [5:45 – 6:00 p.m. CEST]. Abstract #S218.)

Tafasitamab

Tafasitamab (tafa) Plus Lenalidomide (len) and Rituximab (R) for Patients with Relapsed or Refractory Follicular Lymphoma (R/R FL): Results from the Phase 3 inMIND Study
(Session: Indolent and Mantle-Cell Non-Hodgkin Lymphoma - Clinical. June 14, 11:00 – 11:15 a.m. EDT [5:00 – 5:15 p.m. CEST]. Abstract #S230.)

Poster Presentations

Axatilimab

Trial in Progress: A Randomized, Open-Label, Phase 3 Study of Axatilimab Versus Best Available Therapy in Patients with Chronic Graft-Versus-Host Disease After ≥2 Prior Lines of Systemic Therapy
(Session: Poster Session 1. June 13, 12:30 – 1:30 p.m. EDT [6:30 – 7:30 p.m. CEST]. Abstract #PF1090.)

Dynamics of Overall and Organ-Specific Responses to Axatilimab in Chronic Graft-Versus-Host Disease: Analysis from the AGAVE-201 Study
(Session: Poster Session 1. June 13, 12:30 – 1:30 p.m. EDT [6:30 – 7:30 p.m. CEST]. Abstract #PF1035.)

Correlations of Clinician-Reported Responses with Other Response Measures in Patients with Chronic Graft-Versus-Host Disease: An Analysis From the AGAVE-201 Trial
(Session: Poster Session 1. June 13 12:30 – 1:30 p.m. EDT [6:30 – 7:30 p.m. CEST]. Abstract #PF1041.)

The Effects of Prior Lines of Therapy on Clinical Outcomes for Patients with Chronic Graft-Versus-Host Disease Receiving Axatilimab: A Post Hoc Analysis of AGAVE-201
(Session: Poster Session 2. June 14, 12:30 – 1:30 p.m. EDT [6:30 – 7:30 p.m. CEST]. Abstract #PS2029).

INCB057643 (BET)

Bromodomain and Extra-Terminal (BET) Protein Inhibitor, INCB057643, Improves Bone Marrow Function and Shifts Megakaryopoiesis to Erythropoiesis in Patients with Myeloproliferative Neoplasms (MPNs)
(Session: Poster Session 1. June 13, 12:30 – 1:30 p.m. EDT [6:30 – 7:30 p.m. CEST]. Abstract #PF801.)

INCB057643, a Bromodomain and Extra-Terminal Protein Inhibitor, Has Novel Roles in Myeloid Cell Regulation and Immunosuppressive Tumour Environment Remodelling in Myelofibrosis
(Session: Poster Session 2. June 14, 12:30 – 1:30 p.m. EDT [6:30 – 7:30 p.m. CEST]. Abstract #PS1805.)

Safety and Efficacy of Bromodomain and Extra-Terminal (BET) Inhibitor INCB057643 in Patients (pts) with Relapsed or Refractory Myelofibrosis (MF) and Other Advanced Myeloid Neoplasms: A Phase 1 Study
(Session: Poster Session 2. June 14, 12:30 – 1:30 p.m. EDT [6:30 – 7:30 p.m. CEST]. Abstract #PS1822.)

Ponatinib

Impact of Ponatinib Treatment on Pregnancy Outcomes
(Session: Poster Session 2. June 14, 12:30 – 1:30 p.m. EDT [6:30 – 7:30 p.m. CEST]. Abstract #PS1598.)

Ruxolitinib

***JAK2* V617F VAF and Presence of Copy Neutral-LOH at Chromosome 9p (chr9p) Predicts Transformation to Myelofibrosis (MF) in Patients with Polycythemia Vera (PV) Enrolled in REVEAL**
(Session: Poster Session 1. June 13, 12:30 – 1:30 p.m. EDT [6:30 – 7:30 p.m. CEST]. Abstract #PF819.)

Clinical and Gene Expression Patterns Associated with Disease Progression in Patients with Low-Risk Myelofibrosis Enrolled in the Myelofibrosis and Essential Thrombocythemia Observational Study (MOST)
(Session: Poster Session 2. June 14, 12:30 – 1:30 p.m. EDT [6:30 – 7:30 p.m. CEST]. Abstract #PS1808.)

Tafasitamab

CD19 Expression is Retained in Patients with Relapsed/Refractory Follicular or Marginal Zone Lymphoma After Receiving Tafasitamab, Lenalidomide and Rituximab in the inMIND Study
(Session: Poster Session 1. June 13, 12:30 – 1:30 p.m. EDT [6:30 – 7:30 p.m. CEST]. Abstract #PF1006.)

Tafasitamab plus Lenalidomide and Rituximab in Relapsed or Refractory Follicular Lymphoma: A Post Hoc Analysis of Outcomes by POD24 Status from the inMIND Study
(Session: Poster Session 2. June 14, 12:30 – 1:30 p.m. EDT [6:30 – 7:30 p.m. CEST]. Abstract #PS1877.)

More information regarding the 2025 EHA Congress can be found at: https://congress-apps.ehaweb.org/eha2025/en-GB/pag/.

Conference Call and Webcast

Incyte will host an in-person analyst and investor event on Sunday, June 15, 2025 from 6:00 - 7:30 a.m. ET (12:00 - 1:30 p.m. CEST) to discuss key mutCALR data being presented at EHA.

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 Mutations in Calreticulin (mutCALR)

Calreticulin (CALR) is a protein involved in the regulation of cellular calcium levels and normal protein production. 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),[1] a closely related group of clonal blood cancers in which the bone marrow functions abnormally, overproducing blood cells.[2,3] Among two types of MPNs, essential thrombocythemia (ET) and myelofibrosis (MF), mutCALR drives 25-35% of all cases.[2,3]

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 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 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 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 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, 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 March 31, 2025. Incyte disclaims any intent or obligation to update these forward-looking statements.

[1] 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)

[2] 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)

[3] 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)

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