# Data from Across Incyte's Oncology Portfolio Accepted for Presentation at the 2023 ASCO Annual Meeting and EHA2023 Hybrid Congress

May 25, 2023

WILMINGTON, Del.--(BUSINESS WIRE)--May 25, 2023-- Incyte (Nasdaq:INCY) today announced that multiple abstracts featuring data from across its oncology portfolio will be presented at the upcoming 2023 American Society of Clinical Oncology (ASCO) Annual Meeting held June 2-6 in Chicago, and at the European Hematology Association 2023 (EHA2023) Hybrid Congress held in Frankfurt, Germany, from June 8-11 and virtually from June 14-15.

"Our presence at ASCO and EHA illustrates Incyte's ongoing commitment to science that can lead to additional, needed solutions for patients with cancer," said Steven Stein, M.D., Chief Medical Officer, Incyte. "These data underscore the potential of our oncology pipeline, and highlight the variety of approaches we are exploring to advance research in areas where we believe we can have the greatest impact for patients."

Key abstracts accepted by ASCO and EHA include:

**ASCO Abstracts**

Abstracts are available to registered attendees on the ASCO Congress platform. Posters and slides will be available to registered attendees at the scheduled session start time.

**Poster Discussion**

***LIMBER***

**Phase 1/2 Study of the Activin Receptor-Like Kinase (ALK)-2 Inhibitor Zilurgisertib (INCB000928, LIMBER-104) as Monotherapy or with Ruxolitinib (RUX) in Patients (pts) with Anemia due to Myelofibrosis (MF)** (Abstract #7017. Session: Hematologic Malignancies—Leukemia, Myelodysplastic Syndromes, and Allotransplant. Monday, June 5, 12:30 p.m. – 2:00 p.m. ET)

**Poster Presentations**

***CK0804***

**Phase 1b, Open-Label Study of Add-On Therapy with CK0804 in Participants with Myelofibrosis, with Suboptimal Response to Ruxolitinib** (Abstract #TPS7087. Session: Hematologic Malignancies—Leukemia, Myelodysplastic Syndromes, and AllotransplantMonday, June 5, 9:00 a.m. – 12:00 p.m. ET)[1]

***Immuno-oncology (IO)***

**A Phase 1/2 Study of Retifanlimab (INCMGA00012, Anti–PD-1), INCAGN02385 (Anti–LAG-3), and INCAGN02390 (Anti–TIM-3) Combination Therapy in Patients (Pts) with Advanced Solid Tumors** (Abstract #2599. Session: Developmental Therapeutics—ImmunotherapySaturday, June 3, 9:00 a.m. – 12:00 p.m. ET)

***Itacitinib***

**Rates of Cytokine Release Syndrome (CRS) and Immune Effector Cell–Associated Neurotoxicity Syndrome (ICANS) from Center for International Blood and Marrow Transplant Research (CIBMTR) Data on U.S. Subjects (SUBJ) with Lymphoma Following Chimeric Antigen Receptor T Cell (CAR-T) Therapy** (Abstract #7528. Session: Hematologic Malignancies—Lymphoma and Chronic Lymphocytic LeukemiaMonday, June 5, 9:00 a.m. – 12:00 p.m. ET)

***LIMBER***

**Bromodomain and Extra-Terminal (BET) Inhibitor INCB057643 (LIMBER-103) in Patients (pts) with Relapsed or Refractory Myelofibrosis (R/R MF) and Other Advanced Myeloid Neoplasms: A Phase 1 Study** (Abstract #7069. Session: Hematologic Malignancies—Leukemia, Myelodysplastic Syndromes, and Allotransplant. Monday, June 5, 9:00 a.m. – 12:00 p.m. ET)

**EHA Abstracts**

Abstracts are available on the EHA2023 Congress platform and accessible for on-demand viewing until August 15, 2023.

**Oral Presentations**

***Ponatinib***

**PhALLCON: A Phase 3 Study Comparing Ponatinib vs Imatinib in Newly Diagnosed Ph+ALL** (Abstract #S110. Session: Immune Therapeutic Treatment in ALL. Friday, June 9, Date, 8:45 a.m. – 9:00 a.m. ET)[2]

***Ruxolitinib***

**Ruxolitinib in Pediatric Patients with Treatment-Naive or Steroid Refractory Chronic Graft-Versus-Host Disease: Primary Findings from the Phase 2 REACH 5 Study** (Abstract #S245. Session: SCT Clinical. Saturday, June 10, 5:30 a.m. – 6:45 a.m. ET)[3]

**Poster Presentations**

***LIMBER***

**Bromodomain and Extra-Terminal (BET) Inhibitor INCB057643 in Patients (pts) with Relapsed or Refractory Myelofibrosis (R/R-MF) and Other Advanced Myeloid Neoplasms: A Phase 1 Study** (Abstract #P1055. Session: Myeloproliferative Neoplasms - Clinical. Friday, June 9, 12:00 p.m. – 1:00 p.m. ET)

**Phase 1/2 Study of the Activin Receptor-like Kinase 2 (ALK2) Inhibitor Zilurgisertib (INCB000928, LIMBER-104) as Monotherapy or with Ruxolitinib in Patients with Anemia due to Myelofibrosis** (Abstract #P1022. Session: Myeloproliferative Neoplasms - Clinical. Friday, June 9, 12:00 p.m. – 1:00 p.m. ET)

***Parsaclisib***

**A Phase 2, Multicenter, Single-Arm Study of Parsaclisib, a PI3Kδ Inhibitor, in Relapsed or Refractory Follicular Lymphoma in China: Updated Results from the Study** (Abstract #P1099. Session: Indolent and Mantle-Cell Non-Hodgkin Lymphoma - Clinical. Friday, June 9, 12:00 p.m. – 1:00 p.m. ET)[4]

***Ponatinib***

**Multicenter, Prospective and Retrospective Observational Cohort Study of Ponatinib in Patients with CML in Italy: Long-Term Follow-Up Results of the OITI Trial** (Abstract #P663. Session: Chronic Myeloid Leukemia - Clinical. Friday, June 9, 12:00 p.m. – 1:00 p.m. ET)

**Early Cytogenetic or Molecular Landmark Response to Ponatinib Treatment Predicts Outcomes in Heavily Pretreated Patients with Chronic-Phase Chronic Myeloid Leukemia in PACE: 5-Year Data** (Abstract #P670. Session: Chronic Myeloid Leukemia – Clinical. Friday, June 9, 12:00 p.m. – 1:00 p.m. ET)[3]

**Post Hoc Analysis of Patient Responses by T315I Mutation Status from the 3-Year Update of the OPTIC Trial: A Dose-Optimization Study of Three Starting Doses of Ponatinib** (Abstract #P662. Session: Chronic Myeloid Leukemia – Clinical. Friday, June 9, 12:00 p.m. – 1:00 p.m. ET)[3]

***Ruxolitinib***

**Characteristics and Clinical Outcomes in Patients (Pts) With Polycythemia Vera (PV) Receiving Ruxolitinib (RUX) after Hydroxyurea (HU): A Longitudinal Analysis from REVEAL** (Abstract #P1032. Session: Myeloproliferative Neoplasms – Clinical. Friday, June 9, 12:00 p.m. – 1:00 p.m. ET)

**Disease Progression and Leukemic Transformation in Patients with Lower-Risk Myelofibrosis (MF): An Analysis from MOST** (Abstract #P1045. Session: Myeloproliferative Neoplasms – Clinical. Friday, June 9, 12:00 p.m. – 1:00 p.m. ET)

**Treatment Comparison of Hydroxyurea vs Ruxolitinib in Essential Thrombocythemia (ET): A Matched Cohort Analysis** (Abstract #P1046. Session: Myeloproliferative Neoplasms – Clinical. Friday, June 9, 12:00 p.m. – 1:00 p.m. ET)

***Tafasitamab***

**Comprehensive Molecular Subtyping of Diffuse Large B-Cell Lymphoma Cell Lines and Association with Tafasitamab Activity** (Abstract #P1227. Session: Lymphoma Biology & Translational Research. Friday, June 9, 12:00 p.m. – 1:00 p.m. ET)

**Five-Year Efficacy and Safety of Tafasitamab in Patients with Relapsed or Refractory DLBCL: Final Results from the Phase 2 L-MIND Study** (Abstract #P1138. Session: Aggressive Non-Hodgkin Lymphoma – Clinical. Friday, June 9, 12:00 p.m. – 1:00 p.m. ET)[5]

For full session details and data presentation listings, please see the ASCO (https://conferences.asco.org) and EHA2023 (https://ehaweb.org/congress) online programs.

**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 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 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 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).

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 diffuse large B-cell lymphoma (DLBCL) who are not eligible for autologous stem cell transplant (ASCT).

Tafasitamab is being clinically investigated as a therapeutic option in B-cell malignancies in several ongoing combination 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 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 trademark of Incyte.

**About LIMBER**
Incyte is a leader in the discovery and development of therapies for patients with myeloproliferative neoplasms (MPNs) and graft-versus-host disease (GVHD). The LIMBER clinical trial program is designed to evaluate multiple monotherapy and combination strategies to improve and expand treatments for patients with MPNs and GVHD. These include ruxolitinib-based combinations with BET and ALK2, new therapeutic options including axatilimab and novel targets such as mutant CALR.

**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; the effects of the COVID-19 pandemic and measures to address the pandemic on Incyte and its partners' clinical trials, supply chain, other third-party providers and development and discovery operations; determinations made by the U.S. FDA and other regulatory authorities outside of the United States; 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 March 31, 2023. Incyte disclaims any intent or obligation to update these forward-looking statements.

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[1] Cellenkos-sponsored abstract

[2] Takeda-sponsored abstract

[3] Novartis-sponsored abstract

[4] Innovent-sponsored abstract

6 MorphoSys-sponsored abstract

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**Media**
Catalina Loveman

+1 302 498 6171
cloveman@incyte.com

**Investors**
Greg Shertzer
+1 302 498 4779
gshertzer@incyte.com

Source: Incyte