Incyte Announces Data from Across its Oncology Portfolio will be Presented at the AACR Annual Meeting 2023

March 14, 2023

WILMINGTON, Del.--(BUSINESS WIRE)--Mar. 14, 2023-- Incyte (Nasdaq:INCY) today announced that multiple abstracts from across its oncology portfolio will be presented during the upcoming American Association for Cancer Research (AACR) Annual Meeting 2023, held April 14-19, in Orlando, Florida.

“As Incyte continues to advance research in areas where we believe we can have the biggest impact for patients, we look forward to sharing new pre-clinical and clinical data from our expansive oncology portfolio at this year’s AACR,” said Steven Stein, M.D., Chief Medical Officer, Incyte. “Notably, a plenary session will feature data on pemigatinib in previously-treated solid tumors with activating FGFR1–3 alterations, and five-year results from the L-MIND study of tafasitamab (Monjuvi®) in patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) will be highlighted in a late-breaking oral presentation.”

Key abstracts from Incyte-sponsored and partner programs include:

Oral Presentation in a Plenary Session

Pemigatinib

Clinical and Translational Findings of Pemigatinib in Previously Treated Solid Tumors with Activating FGFR1–3 Alterations in the FIGHT-207 Study (Abstract #CT016. Session: Novel Biomarker-Driven Molecularly Targeted Therapy Trials. Tuesday, April 18, 2023, 10:15 a.m. – 10:30 a.m. ET)

Oral Presentation

INCB123667 (CDK2)

Development of a CDK2-Selective Small Molecule Inhibitor INCB123667 for the Treatment of CCNE1hi Breast Cancers (Abstract #1143. Session: Small Molecule Therapeutic Agents. Sunday, April 16, 2023, 3:52 p.m. – 4:07 p.m. ET)

Tafasitamab

Five-Year Safety and Efficacy of Tafasitamab in Patients with Relapsed or Refractory DLBCL: Final Results from the Phase 2 L-MIND Study[1] (Abstract #CT022. Session: Novel Clinical Trials for Hematological Malignancies. Sunday, April 16, 2023, 3:20 p.m. – 3:30 p.m. ET)

Poster Presentations

INCA33890 (PD-1×TGFbR2)

INCA33890, a Novel PD-1×TGFbR2 Bispecific Antibody Conditionally Antagonizes TGF Signaling in Primary Immune Cells Co-expressing PD-1 (Abstract #2936. Session: Therapeutic Antibodies 2. Monday, April 17, 2023, 1:30 p.m. – 5:00 p.m. ET)

INCB098377 (PI3Kγ)

Discovery of INCB098377: a Potent Inhibitor of Phosphoinositide 3-Kinase-Gamma (Abstract #5162. Session: Modifiers of the Tumor Microenvironment. Tuesday, April 18, 2023, 1:30 p.m. – 5:00 p.m. ET)

LIMBER (MPN)

A Phase 1 Study of Ruxolitinib in Combination with Abemaciclib for Patients with Primary or Post-Polycythemia Vera/Essential Thrombocythemia Myelofibrosis (Abstract #CT242. Session: Phase 1 and First-in-Human Clinical Trials in Progress. Tuesday, April 18, 2023, 1:30 p.m. – 5:00 p.m. ET)

Preclinical Characterization of the BET Inhibitor, INCB057643, in Combination with Ruxolitinib for Treatment of Myeloproliferative Neoplasms (MPN) (Abstract #6274. Session: Epigenetics. Wednesday, April 19, 2023, 9:00 a.m. – 12:30 p.m. ET)

Pemigatinib

Drug Combination Screen Identifies Pemigatinib, an FGFR Inhibitor, as a Mechanism to Overcome KRASG12C Inhibitor Resistance in Lung Cancer (Abstract #412. Session: Drug Resistance in Molecular Targeted Therapies 2. Sunday, April 16, 2023, 1:30 p.m. – 5:00 p.m. ET)

Pemigatinib, an FGFR Inhibitor, Overcomes Resistance to KRASG12C Inhibitors in Mesenchymal-Like NSCLC Tumors (Abstract #430. Session: Drug Resistance in Molecular Targeted Therapies 2. Sunday, April 16, 2023, 1:30 p.m. – 5:00 p.m. ET)

P-Selectin Glycoprotein Ligand-1

P-Selectin Glycoprotein Ligand-1 Modulates the Functions of Human T Cells and Macrophages in Vitro (Abstract #6373. Session: Immune Checkpoints. Wednesday, April 19, 2023, 9:00 a.m. – 12:30 p.m. ET)

Tafasitamab

Combination of BTK Inhibitor Orelabrutinib, Anti-CD19 Antibody Tafasitamab, and IMiD Lenalidomide for the Treatment of B Cell Malignancies[2] (Abstract #4013. Session: Tyrosine Kinase and Phosphatase Inhibitors 1. Tuesday, April 18, 2023, 9:00 a.m. – 12:30 p.m. ET)

Preclinical Study of CD19 Detection Methods Using Monoclonal Antibodies Post Tafasitamab Treatment1 (Abstract #6329. Session: Anticancer Immunotherapeutics. Wednesday, April 19, 2023, 9:00 a.m. – 12:30 p.m. ET)

Zilurgisertib

Clinical Trial Simulation to Inform Dose Selection of Zilurgisertib, an ALK2 inhibitor, in Patients with Anemia Due to Myelofibrosis (MF) (Abstract #CT243. Session: Phase 1 and First-in-Human Clinical Trials in Progress. Tuesday, April 18, 2023, 1:30 p.m. – 5:00 p.m. ET)

For registered attendees, the virtual meeting platform and all on-demand sessions will be available through July 19, 2023. More information regarding the AACR Annual Meeting 2023 can be found at https://www.aacr.org/meeting/aacr-annual-meeting-2023/.

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[3]. 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 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 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[3].

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 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 for the year ending December 31, 2022. Incyte disclaims any intent or obligation to update these forward-looking statements.

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[1] MorphoSys Sponsored Abstract

[2] Innocare Sponsored Abstract

[3] Jakafi (ruxolitinib) tablets: Prescribing Information. U.S. Food and Drug Administration

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

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Media
Catalina Loveman
+1 302 498 6171
cloveman@incyte.com

Investors
Christine Chiou
+1 302 274 4773
cchiou@incyte.com

Source: Incyte Corporation