More than 50 Abstracts from Incyte's Robust Oncology Portfolio to be Featured at the 64th ASH Annual Meeting

November 3, 2022

- Plenary Scientific Session to highlight Incyte-discovered novel anti-mutant CALR-targeted monoclonal antibody INCA033989

- Data from three of the Company's LIMBER studies evaluating ruxolitinib in combination with parsaclisib and its ALK2 and BET inhibitors to be presented

- Incyte to host an in-person analyst and investor event on Sunday, December 11, 2022, from 8:00-9:30 p.m. CT to discuss key data presentations at ASH

WILMINGTON, Del.--(BUSINESS WIRE)--Nov. 3, 2022-- Incyte (Nasdaq:INCY) will present data from its oncology portfolio at the upcoming 64th American Society of Hematology Annual Meeting (ASH 2022), held December 10-13, 2022, in New Orleans and virtually. More than 50 abstracts featuring Incyte compounds will be presented, highlighting its robust portfolio and clinical development programs.

"The data to be presented at ASH illustrate the scientific depth and progress made across several of our key programs, including ruxolitinib (Jakafi®), parsaclisib, tafasitamab (Monjuvi®/Minjuvi®), pemigatinib (Pemazyre®) as well as our LIMBER studies, which are evaluating new targets and combination strategies to expand treatment options for patients with myeloproliferative neoplasms (MPNs) and graft-versus-host disease (GVHD)," said Peter Langmuir, M.D., Group Vice President, Oncology Targeted Therapeutics, Incyte. "Notably, the plenary scientific session at ASH will feature INCA033989, an Incyte-developed, novel anti-mutant CALR-targeted monoclonal antibody. Additionally, a combination study evaluating ruxolitinib with parsaclisib will be featured as an oral presentation, and two studies evaluating ruxolitinib with INCB000928 and INCB057643, our ALK2 and BET inhibitors, respectively, will also be presented. These presentations highlight our advancing portfolio and comprehensive approach to identifying potential new treatments for patients with cancer."

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

Plenary Scientific Session

INCA033989

Discovery of INCA033989, a Monoclonal Antibody that Selectively Antagonizes Mutant Calreticulin Oncogenic Function in Myeloproliferative Neoplasms (MPNs) (Abstract #6. Plenary Scientific Session: Hematology Disease Topics & Pathways: Research, Diseases, Therapies, Myeloid Malignancies. Sunday, December 11, 3:00 p.m. EST)

Oral Presentations

LIMBER (MPN)

Efficacy and Safety of Add-on Parsaclisib to Ruxolitinib Therapy in Myelofibrosis Patients With Suboptimal Response to Ruxolitinib: Final Results From a Phase 2 Study (Abstract #236. Session: 634. Myeloproliferative Syndromes: Clinical and Epidemiological: Latest Data for Combination and Emerging Targeted Therapies in Myelofibrosis. Saturday, December 10, 3:15 p.m. EST)

Ruxolitinib (GVHD)

Ruxolitinib in Pediatric Patients with Treatment-Naïve or Steroid-Refractory Acute Graft-Versus-Host Disease: Primary Findings from the Phase 1/2 REACH 4 Study[1] (Abstract #572. Session: 722. Allogeneic Transplantation: Acute and Chronic GVHD, Immune Reconstitution: Critical Advances in GVHD Management. Sunday, December 11, 2022, 1:15 p.m. EST)

Ruxolitinib (MPN)

Siremadlin, a Human Double Minute-2 (HDM2) Inhibitor, Added to Ruxolitinib After Suboptimal Response to Ruxolitinib Alone in Patients with Myelofibrosis: Results from Part 1 of the Phase 1/2 ADORE Study[1] (Abstract #239**.** Session: 634. Myeloproliferative Syndromes: Clinical and Epidemiological: Latest Data for Combination and Emerging Targeted Therapies in Myelofibrosis. Saturday, December 10, 2022, 4:00 p.m. EST)

Tafasitamab

MRD-Negativity as a Potential Surrogate Endpoint After Frontline DLBCL Therapy: Pooled Analysis & Implications for Clinical Trial Design[2] (Abstract #322. Session: 627. Aggressive Lymphomas: Clinical and Epidemiological: Prognostication and Risk Stratification of Aggressive B-cell NHL. Saturday, December 10, 5:45 p.m. EST)

Ponatinib

Three-Year Update From the OPTIC Trial: A Dose-Optimization Study of 3 Starting Doses of Ponatinib[3] (Abstract #620. Session: 632. Chronic Myeloid Leukemia: Clinical and Epidemiological: Longer Term Response, TFR, Pregnancy, and Disparities. Sunday, December 11, 5:45 p.m. EST)

Itacitinib

Itacitinib and Corticosteroids as Initial Treatment for Chronic Graft-Versus-Host Disease: Phase 1/2 results from GRAVITAS-309 (Abstract

#771. Session: 722. Allogeneic Transplantation: Acute and Chronic GVHD, Immune Reconstitution: Novel Therapies for Graft-versus-Host Disease. Monday, December 12, 12:00 p.m. EST)

Poster Presentations

All accepted posters in Poster I sessions are available for in-person participants from 6:30 p.m. – 8:30 p.m. EST and for registered virtual participants from 10:00 a.m. – 8:30 p.m. EST on Saturday, December 10. All accepted posters in Poster II sessions are available for in-person participants from 7:00-9:00 p.m. EST and for registered virtual participants from 10:00 a.m. – 9:00 p.m. EST on Sunday, December 11. All accepted posters in Poster III sessions are available for in-person participants from 7:00–9:00 p.m. EST and for registered virtual participants from 10:00 a.m. – 9:00 p.m. EST on Monday, December 12.

LIMBER (MPN)

A Phase 1/2 study of INCB000928 as Monotherapy or Combined with Ruxolitinib (RUX) in Patients (Pts) with Anemia Due to Myelofibrosis (MF) (Abstract #1714. Session: 634. Myeloproliferative Syndromes: Clinical and Epidemiological: Poster I)

INCB057643 Monotherapy in Patients with Relapsed or Refractory Myelofibrosis: A Phase 1 Study (Abstract #4358. Session: 634. Myeloproliferative Syndromes: Clinical and Epidemiological: Poster III)

Ruxolitinib (GVHD)

Early Versus Late Treatment with Ruxolitinib in Patients with Steroid-Refractory Acute Graft-Versus-Host Disease: A Post Hoc Analysis from the Randomized Phase 3 REACH2 Study (Abstract #2079. Session: 722. Allogeneic Transplantation: Acute and Chronic GVHD, Immune Reconstitution: Poster I)

Early Versus Late Treatment with Ruxolitinib in Patients with Steroid-Refractory Chronic Graft-Versus-Host Disease: A Post Hoc Analysis from the Randomized, Phase 3 REACH3 Study (Abstract #4714. Session: 722. Allogeneic Transplantation: Acute and Chronic GVHD, Immune Reconstitution: Poster III)

The Probability of Being in Response (PBR): A Novel Efficacy Endpoint for Chronic Graft Versus Host Disease (GVHD) Applied to the REACH3 study of Ruxolitinib Versus BAT[1] (Abstract #4720. Session: 722. Allogeneic Transplantation: Acute and Chronic GVHD, Immune Reconstitution: Poster III)

Ruxolitinib (MPN)

Direct and Indirect Costs of Patients with Myeloproliferative Neoplasm Diseases (Abstract #2308. Session: 906. Outcomes Research—Myeloid Malignancies: Poster I)

Characteristics and Clinical Outcomes in Patients (Pts) With Polycythemia Vera (PV) Receiving Ruxolitinib (RUX) after Hydroxyurea (HU): A Longitudinal Analysis from REVEAL (Abstract #3031. Session: 634. Myeloproliferative Syndromes: Clinical and Epidemiological: Poster II)

Disease Progression and Leukemic Transformation in Patients with Lower-Risk Myelofibrosis (MF): An Analysis From MOST (Abstract #3039. Session: 634. Myeloproliferative Syndromes: Clinical and Epidemiological: Poster II)

Real-World Use of Ruxolitinib in Patients with Myelofibrosis who had Anemia or Thrombocytopenia at US Community Practices (Abstract #3630. Session: 906. Outcomes Research—Myeloid Malignancies: Poster II)

Prediction of Resistance to Hydroxyurea Therapy in Patients with Polycythemia Vera: A Machine Learning Study (PV-AIM)[1] (Abstract #3036. Session: 634. Myeloproliferative Syndromes: Clinical and Epidemiological: Poster II)

Ruxolitinib (Ph-like ALL)

A Phase 2 Study of Ruxolitinib with Chemotherapy in Children with Philadelphia Chromosome-Like Acute Lymphoblastic Leukemia (AALL1521/INCB18424-269): Biologic Characteristics and Minimal Residual Disease Response of Patients with non-CRLF2-Rearranged JAK Pathway Alterations (Abstract #2725. Session: 614. Acute Lymphoblastic Leukemias: Therapies, Excluding Transplantation and Cellular Immunotherapies: Poster II)

Parsaclisib

Safety and Efficacy of Parsaclisib in Combination with Rituximab, Bendamustine + Rituximab, or Ibrutinib in Patients with Previously Treated B-Cell Lymphoma: Analysis of a Phase 1 Dose-Finding Study (CITADEL 112) (Abstract #4202. Session: 623. Mantle Cell, Follicular, and Other Indolent B Cell Lymphomas: Clinical and Epidemiological: Poster III)

Tafasitamab

***first*MIND: Final Analysis from a Phase 1b, Open-Label, Randomized Study to Assess Safety of Tafasitamab or Tafasitamab + Lenalidomide in Addition to R-CHOP in Patients with Newly Diagnosed Diffuse Large B-Cell Lymphoma**[2] (Abstract #1619. Session: 626. Aggressive Lymphomas Prospective Therapeutic Trials: Poster I)

***front*MIND: A Phase III, Multicenter, Randomized, Double-Blind Study of Tafasitamab + Lenalidomide + R-CHOP versus R-CHOP Alone for Newly Diagnosed High-Intermediate and High-Risk Diffuse Large B-Cell Lymphoma**[2] (Abstract #2947. Session: 626. Aggressive Lymphomas: Prospective Therapeutic Trials: Poster II)

L-MIND: A Safety and Efficacy Analysis of Tafasitamab in Patients with Relapsed/Refractory Diffuse Large B-Cell Lymphoma (R/R DLBCL) Receiving Treatment for at Least 2 Years[2] (Abstract #2937. Session: 626. Aggressive Lymphomas: Prospective Therapeutic Trials: Poster II)

Blocking the CD47-SIRPa Axis Enhances Tafasitamab-Mediated Phagocytosis[2] (Abstract #4185. Session: 622. Lymphomas: Translational–Non-Genetic: Poster III)

Ultrasensitive MRD Profiling Predicts Outcomes in DLBCL after Frontline Therapy with Tafasitamab in Combination with Lenalidomide and R-CHOP[2] (Abstract #1519. Session: 621. Lymphomas: Translational—Molecular and Genetic: Poster I)

Pemigatinib

FIGHT-203, an Ongoing Phase 2 Study of Pemigatinib in Patients with Myeloid/Lymphoid Neoplasms (MLNs) with Fibroblast Growth Factor Receptor 1 (FGFR1) Rearrangement (MLNFGFR1): A Focus on Centrally Reviewed Clinical and Cytogenetic Responses in Previously Treated Patients (Abstract #1732. Session: 634. Myeloproliferative Syndromes: Clinical and Epidemiological: Poster I)

Myeloid/Lymphoid Neoplasms (MLNs) with Fibroblast Growth Receptor 1 (FGFR1) Rearrangement (MLN-FGFR1): A US Real-World Retrospective Cohort Study (Abstract #3048. Session: 634. Myeloproliferative Syndromes: Clinical and Epidemiological: Poster II)

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 Sunday, December 11, 2022, from 8:00-9:30 p.m. CT (9:00–10:30 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 90 days.

Conference call details will be provided on our website.

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 Leadership In MPNs and GVHD BEyond Ruxolitinib (LIMBER) program is designed to evaluate multiple monotherapy and combination strategies to improve and expand treatments for patients with MPNs and GVHD. The program currently has three key areas of focus: development of a new, once-daily formulation of ruxolitinib; ruxolitinib-based combinations with new targets such as PI3Kδ, BET and ALK2; and new therapeutic options such as Mutant CALR.

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[4].

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 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*. 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.

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

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 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 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 September 30, 2022. Incyte disclaims any intent or obligation to update these forward-looking statements.

[1] Novartis-sponsored abstract

[2] MorphoSys-sponsored abstract

[3] Takeda-sponsored abstract

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

View source version on businesswire.com: https://www.businesswire.com/news/home/20221103005878/en/

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

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

Source: Incyte