

Data from Incyte's Robust and Progressing Oncology Portfolio to be Presented at 2022 EHA Annual Meeting

May 26, 2022

WILMINGTON, Del.--(BUSINESS WIRE)--May 26, 2022-- Incyte (Nasdaq:INCY) today announced that multiple abstracts featuring data from its oncology portfolio will be presented at the upcoming European Hematology Association 2022 (EHA2022) Congress (June 9-17; virtual and in Vienna).

"We are committed to advancing science that can lead to solutions for patients with serious unmet medical needs, including those with cancer," said Steven Stein, M.D., Chief Medical Officer, Incyte. "For that reason, we look forward to convening with the oncology community and presenting data from across our portfolio, including both Incyte-led and partnered programs."

Key abstracts accepted by EHA include:

Oral Presentation

Long-term Efficacy and Safety Results from an Ongoing Open-Label Phase 2 Study of Parsaclisib for the Treatment of Autoimmune Hemolytic Anemia (AIHA) (Abstract #S286. Session: Transfusion and Autoimmune Hemolytic Anemia. Session Time: Friday, June 10, 11:30 a.m. - 12:45 p.m.)

Poster Presentations

A Real-World Evaluation of the Association Between Elevated Blood Counts and Thrombotic Events in Polycythemia Vera: An Analysis of Data from the Reveal Study (Abstract #P1062. Session: Myeloproliferative neoplasms – Clinical)

Does Early Intervention in Myelofibrosis Impact Outcomes? A Pooled Analysis of the COMFORT 1 and 2 Studies (Abstract #P1037. Session: Myeloproliferative neoplasms - Clinical)

Ruxolitinib Demonstrates a Greater Corticosteroid-Sparing Effect than Best Available Therapy in Patients with Corticosteroid-Refractory/Dependent Chronic Graft-Vs-Host Disease¹ (Abstract #P1389. Session: Stem cell transplantation - Clinical)

Real-World Safety of Ruxolitinib in Patients with Intermediate or High Risk of Primary Myelofibrosis, Post-Polycythemia Vera Myelofibrosis or Post-Essential Thrombocythemia Myelofibrosis in China¹ (Abstract #P1047. Session: Myeloproliferative neoplasms - Clinical)

Efficacy and Safety of Parsaclisib-Ruxolitinib Combination Therapy in Myelofibrosis Patients with Low vs Higher Baseline Platelet Count: A Subgroup Analysis of Data from a Phase 2 Study (Abstract #P1063. Session: Myeloproliferative neoplasms - Clinical)

A Phase 1 Study Evaluating Safety and Efficacy of Parsaclisib in Combination with Bendamustine + Obinutuzumab in Patients with Relapsed or Refractory Follicular Lymphoma (CITADEL-102) (Abstract #P1104. Session: Indolent and mantle-cell non-Hodgkin lymphoma -Clinical)

A Phase 1 Study of Parsaclisib in Combination with Investigator Choice of Rituximab, Bendamustine + Rituximab, or Ibrutinib in Patients with Previously Treated B-Cell Lymphoma (CITADEL-112): Preliminary Safety Results (Abstract #P1102. Session: Indolent and mantle-cell non-Hodgkin lymphoma - Clinical)

inMIND: A Phase 3 Study of Tafasitamab Plus Lenalidomide and Rituximab Versus Placebo Plus Lenalidomide and Rituximab for Relapsed/Refractory Follicular Lymphoma (FL) or Marginal Zone Lymphoma (MZL) (Abstract #P1103. Session: Indolent and mantle-cell non-Hodgkin lymphoma - Clinical)

Real-Life Effectiveness and Safety Outcomes of Ponatinib Treatment in Patients with Chronic Myeloid Leukemia (CML) and Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (PH+ALL): 5-Year-Data from a Belgian Registry (Abstract #P699. Session: Chronic myeloid leukemia - Clinical)

Dose Modification Dynamics of Ponatinib in Patients with Chronic-Phase Chronic Myeloid Leukemia (CP-CML) from the PACE and OPTIC Trials² (Abstract #P707. Session: Chronic myeloid leukemia - Clinical)

All (e)Poster presentations will be made available as of Friday, June 10, 2022, at 3:00 a.m. EST and will be accessible for on-demand viewing until Monday, August 15, 2022, on the Congress platform. For full session details and data presentation listings, please see the EHA2022 online program (https://ehaweb.org/congress/eha2022-hybrid/eha2022-congress/).

About Ruxolitinib (Jakafi®)

Ruxolitinib (Jakafi[®]) is a first-in-class 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, in adults with intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF, for treatment of steroid-refractory acute GVHD in adult and pediatric patients 12 years and older and for the treatment of 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 U.S. and by Novartis as Jakavi[®] (ruxolitinib) outside the U.S. Jakafi is a registered trademark of Incyte. Jakavi is a registered trademark of Novartis AG in countries outside the U.S.

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 ASCT. This indication is approved under accelerated approval based on overall response rate. Full approval for this indication may be contingent upon results in a confirmatory trial(s).

In Europe, Minjuvi[®] (tafasitamab) received conditional approval, 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.

Minjuvi[®] and Monjuvi[®] 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 the EU.

XmAb[®] is a registered trademark of Xencor, Inc.

About Ponatinib (Iclusig[®]) 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; 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 Parsaclisib

Parsaclisib is a potent, highly selective, next-generation investigational novel oral inhibitor of phosphatidylinositol 3-kinase delta (PI3Kδ). It is currently under evaluation as a monotherapy in non-Hodgkin lymphomas and autoimmune hemolytic anemia, and in combination with ruxolitinib and tafasitamab for myelofibrosis and non-Hodgkin lymphomas, respectively.

In December 2018, Innovent and Incyte entered into a strategic collaboration for three clinical-stage product candidates, including parsaclisib. Under the terms of the agreement, Innovent has received the rights to develop and commercialize parsaclisib and two other assets in Mainland China, Hong Kong, Macau and Taiwan.

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 the Company's or partner company's ongoing clinical development pipeline, and 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, its presentation plans for the upcoming EHA meeting and its goal of improving the lives of patients, contain predictions, estimates and other forward-looking statements.

These forward-looking statements are based on the Company'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 the Company's 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 the Company's products; the acceptance of the Company's products in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; and other risks detailed from time to time in the Company'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, 2022. The Company disclaims any intent or obligation to update these forward-looking statements.

¹ Novartis-sponsored abstract

² Takeda-sponsored abstract

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