More than 35 Abstracts from Incyte’s Oncology Portfolio Accepted for Presentation at the 63rd Annual ASH Meeting and Exposition

Numerous oral presentations highlighting data for tafasitamab, parsaclisib, ruxolitinib, pemigatinib, itacitinib and ponatinib to be highlighted during the Congress

WILMINGTON, Del.--(BUSINESS WIRE)-- Incyte (Nasdaq:INCY) today announced that numerous abstracts highlighting data from its oncology portfolio will be presented at the upcoming 63rd American Society of Hematology Annual Meeting and Exposition (ASH 2021), held December 11–14, 2021 in Atlanta, Georgia and virtually.

“We are excited for the opportunity to present, along with our partners, more than 35 abstracts and share progress from Incyte’s oncology portfolio at this year’s ASH meeting,” said Peter Langmuir, M.D., Group Vice President, Oncology Targeted Therapeutics, Incyte. “The oral presentations, including new data from the CITADEL program evaluating parsaclisib in three types of lymphoma as well as results from the RE-MIND2 study of tafasitamab plus lenalidomide in patients with relapsed or refractory diffuse large B-cell lymphoma, highlight the strength of our robust oncology portfolio and underscore our commitment to addressing urgent medical needs for people with cancer.”

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

**Oral Presentations**

**Parsaclisib**

**Efficacy and Safety of Parsaclisib in Patients with Relapsed or Refractory Marginal Zone Lymphoma: Primary Analysis from a Phase 2 Study (CITADEL-204)** (Abstract #44. Session: 623. Mantle Cell, Follicular, and Other B-Cell Lymphomas: Clinical and Epidemiological: Targeted Therapy in Low Grade
Efficacy and Safety of Parsaclisib in Patients with Relapsed or Refractory Mantle Cell Lymphoma Not Previously Treated With a BTK Inhibitor: Primary Analysis From a Phase 2 Study (CITADEL-205) (Abstract #382. Session: 623. Mantle Cell, Follicular, and Other B-Cell Lymphomas: Clinical and Epidemiological: Front-line Induction Therapy and Novel Agents After Relapse. Sunday, December 12, 10:15 a.m. ET)

Efficacy and Safety of Parsaclisib in Patients With Relapsed or Refractory Follicular Lymphoma: Primary Analysis From a Phase 2 Study (CITADEL-203) (Abstract #813. Session: 623. Mantle Cell, Follicular, and Other B-Cell Lymphomas: Clinical and Epidemiological: Front-line Induction Therapy and Novel Agents After Relapse. Monday, December 13, 5:00 p.m. ET)

Pemigatinib: Myeloproliferative Neoplasms (MPN)

A Phase 2 Study of Pemigatinib (FIGHT-203; INCB054828) in Patients with Myeloid/Lymphoid Neoplasms (MLNs) with Fibroblast Growth Factor Receptor 1 (FGFR1) Rearrangement (MLNFGFR1) (Abstract #385. Session: 634. Myeloproliferative Syndromes: Clinical and Epidemiological: Novel Therapies for MPNs and JAK Inhibitors for Myelofibrosis. Sunday, December 12, 9:30 a.m. ET)

Ponatinib

Post hoc Analysis of Responses to Ponatinib in Patients with Chronic-Phase Chronic Myeloid Leukemia (CP-CML) by Baseline BCR-ABL1 level and Baseline Mutation Status in the OPTIC Trial1 (Abstract #307. Session:#623. Chronic Myeloid Leukemia: Clinical and Epidemiological: Mechanisms of Resistance and Expanded Therapies. Saturday, December 11, 4:00 p.m. ET)

Ruxolitinib: Graft-Versus-Host Disease (GVHD)

Validation of Amphiregulin as a Monitoring Biomarker During Treatment of Life-Threatening Acute GVHD: A Secondary Analysis of 2 Prospective Clinical Trials (Abstract #259. Session: 722. Allogeneic Transplantation: Acute and Chronic GVHD, Immune Reconstitution: Treatment of Acute and Chronic Graft vs. Host Disease. Saturday, December 11, 2:00 p.m. ET)

Ruxolitinib: Myeloproliferative Neoplasms (MPN)

The Interaction Between IPSS Score and JAK2 Mutation Identifies Patients at Different
Vascular Risk in Primary Myelofibrosis\(^2\) (Abstract #236. Session: #634. Myeloproliferative Syndromes: Clinical and Epidemiological: Risk Stratification and Prognostication. Saturday, December 11, 2:15 p.m. ET)

A Real-World Evaluation of the Association Between Elevated Blood Counts and Thrombotic Events in Polycythemia Vera (Analysis of Data from the REVEAL Study)\(^3\) (Abstract #239. Session: #634. Myeloproliferative Syndromes: Clinical and Epidemiological: Risk Stratification and Prognostication. Saturday, December 11, 3:00 p.m. ET)

Tafasitamab

Tafasitamab Plus Lenalidomide Versus pola-BR, R2, and CAR-T: Comparison of Outcomes from RE-MIND2, an Observational Retrospective Cohort Study in Relapsed or Refractory Diffuse Large B-Cell Lymphoma\(^3\) (Abstract #183. Session: #905. Outcomes Research-Lymphoid Malignancies: Lymphoma/CLL Real-World Data. Saturday, December 11, 12:30 p.m. ET)

Poster Presentations

All accepted posters in Poster I are available from 9:00 a.m. – 7:30 p.m. ET on Saturday, December 11. All accepted posters in Poster II sessions are available from 9:00 a.m. – 8:00 p.m. ET on Sunday, December 12. All accepted posters in Poster III sessions are available from 9:00 a.m. – 8:00 p.m. ET on Monday, December 13.

INCB000928: Myeloproliferative Neoplasms (MPN)

A Phase 1/2, Open-label, Multicenter Study of INCB000928 Monotherapy in Patients with Anemia due to Myelodysplastic Syndromes or Multiple Myeloma\(^4\) (Abstract #3707. Session: #637. Myelodysplastic Syndromes — Clinical and Epidemiological: Poster III. Monday, December 13)

INCB057643: Myeloproliferative Neoplasms (MPN)

A Phase 1 Study of INCB057643 Monotherapy in Patients with Relapsed or Refractory Myelofibrosis (INCB 57643-103)\(^5\) (Abstract #2574. Session: #634. Myeloproliferative Syndromes: Clinical and Epidemiological: Poster II. Sunday, December 12)

Parsaclisib

A Phase 2, Multicenter, Single-arm, Open-Label study of Parsaclisib, a PI3Kδ inhibitor, in Relapsed or Refractory Follicular Lymphoma in China\(^4\) (Abstract #3536. Session: #623. Mantle Cell,
Follicular, and Other Indolent B Cell Lymphomas: Clinical and Epidemiological: Poster III. Monday, December 13

Ponatinib

Dose Modification Dynamics of Ponatinib in Patients with Chronic-Phase Chronic Myeloid Leukemia (CP-CML) from the PACE and OPTIC Trials (Abstract #2550. Session: 632. Chronic Myeloid Leukemia: Clinical and Epidemiological: Poster II. Sunday, December 12)

Multicenter, Prospective and Retrospective Observational Cohort Study of Ponatinib in Patients with CML in Italy: Primary Analysis of the OITI Trial (Abstract #3603. Session: 632. Chronic Myeloid Leukemia: Clinical and Epidemiological: Poster III. Monday, December 13)

Ruxolitinib: GVHD


Patient-Reported Outcomes (PROs) Among Patients with Steroid-Refractory or Dependent Chronic Graft-vs-Host Disease (cGVHD) Randomized to Ruxolitinib (RUX) vs Best Available Therapy (BAT) (Abstract #3909. Session: #722. Allogeneic Transplantation: Acute and Chronic GVHD, Immune Reconstitution: Poster III. Monday, December 13)

Ruxolitinib: Myeloproliferative Neoplasms (MPN)


Community Versus Academic Practice in Essential Thrombocythemia and Myelofibrosis: Differences in Clinical Characteristics, Diagnosis, Treatment Patterns, and Symptom Burden (Analysis of Data from the MOST Study) (Abstract #1497. Session: 634. Myeloproliferative Syndromes:
ADORE: A Randomized, Open-Label, Phase 1/2 Open-Platform Study Evaluating Safety and Efficacy of Novel Ruxolitinib Combinations in Patients with Myelofibrosis

Characteristics of High-Risk Polycythemia Vera Patients with Suboptimal Response to First-Line Therapy who Switched to Ruxolitinib vs. Those who did not Switch: Findings from PV-SWITCH, a Multinational, Retrospective Chart Review Study

Labor Market Attachment in Patients with Myeloproliferative Neoplasms: A Nationwide Matched Cohort Study

Ruxolitinib + Parsaclisib Combination Studies: Myeloproliferative Neoplasms (MPN)

A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study of Add-On Parsaclisib in Patients with Myelofibrosis who have Suboptimal Response to Ruxolitinib

A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of Ruxolitinib plus Parsaclisib in Patients With JAK- and PI3K-Inhibitor Treatment–Naive Myelofibrosis

Subgroup Analysis from a Phase 2 Study of the Efficacy and Safety of Parsaclisib, a Selective PI3Kδ Inhibitor, in Combination with Ruxolitinib in Patients with Myelofibrosis (MF)

Tafasitamab

inMIND: A Phase 3 Study of Tafasitamab Plus Lenalidomide and Rituximab Versus Placebo plus Lenalidomide and Rituximab for Relapsed/Refractory Follicular or Marginal Zone Lymphoma

Preferences and Perceptions Regarding Treatment Decision-Making for Relapsed or


First-MIND: A Phase Ib, 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 (Abstract #3556. Session:626. Aggressive Lymphomas: Prospective Therapeutic Trials: Poster III. Monday, December 13)

Full abstracts will be available on ASH's website and in a special online-only issue of Blood, ASH’s official journal. More information regarding ASH 2021 can be found on ASH’s website: https://www.hematology.org/meetings/annual-meeting

About Jakafi® (ruxolitinib)

Jakafi® (ruxolitinib) 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 thrombocythemias 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 Monjuvi® (tafasitamab-cxix)

Tafasitamab 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).

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 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.

[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 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 ASH 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 September 30, 2021. The Company disclaims any intent or obligation to update these forward-looking statements.

1 Takeda-sponsored abstract.
2 Novartis-sponsored abstract.
3 MorphoSys-sponsored abstract.
4 Innovent-sponsored abstract.

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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