More than 40 Abstracts from Incyte’s Oncology Portfolio Accepted for Presentation at the 62nd Annual ASH Virtual Meeting

- Numerous abstracts, including 7 oral presentations, highlighting data for ruxolitinib, parsaclisib, tafasitamab and ponatinib to be exhibited

WILMINGTON, Del.--(BUSINESS WIRE)-- Incyte (Nasdaq: INCY) today announced that numerous abstracts highlighting data from its oncology portfolio will be presented at the upcoming 62nd American Society of Hematology Annual Meeting and Exposition (ASH 2020), held virtually December 5–8, 2020.

“We are thankful for the American Society of Hematology’s efforts to hold ASH 2020 – a key event for the scientific community – virtually, and are proud the Incyte portfolio will be represented in more than 40 abstracts,” said Steven Stein, M.D., Chief Medical Officer, Incyte. “The presentations, including the oral presentation of the Phase 3 REACH3 study for ruxolitinib in chronic graft-versus-host disease (GVHD), reflect the strength of our diverse oncology portfolio and our partnerships, and reinforce our commitment to finding solutions that can improve the lives of patients with multiple rare cancers and serious conditions where there is significant medical need.”

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

**Oral Presentations**

**Ruxolitinib: Graft-Versus-Host Disease (GVHD)**

- Ruxolitinib vs Best Available Therapy in Patients with Steroid-Refractory/Steroid-Dependent Chronic Graft-vs-Host Disease (cGVHD): Primary Findings from the Phase 3, Randomized REACH3 Study1

  (Abstract #77, Session: 732. Clinical Allogeneic Transplantation: Results I. Saturday, December 5, 7:30-9:00 a.m. PT)
Ruxolitinib: Myeloproliferative Neoplasms (MPN)

To Treat or Not To Treat? Understanding Treatment Patterns in Patients with Lower-Risk Myelofibrosis Enrolled in the MOST Study (Abstract #152, Session: 904. Outcomes Research – Non-Malignant Conditions: Bleeding, Immune Thrombocytopenia, and Other Hematologic Disorders. Saturday, December 5, 9:30-11:00 a.m. PT)

Mortality and Causes of Death of Patients with Polycythemia Vera: Analysis of the REVEAL Prospective, Observational Study (Abstract #484, Session: 634. Myeloproliferative Syndromes: Clinical: Clinical Trials in Polycythemia Vera. Sunday, December 6, 2:00-3:30 p.m. PT)

Parsaclisib

Phase 2 Study Evaluating the Efficacy and Safety of Parsaclisib in Patients with Relapsed or Refractory Marginal Zone Lymphoma (CITADEL-204) (Abstract #338, Session: 623. Mantle Cell, Follicular, and Other Indolent B-Cell Lymphoma—Clinical Studies: Clinical studies in Waldenstrom's Macroglobulinemia, Marginal Zone Lymphoma and Hairy Cell Leukemia. Sunday, December 6, 9:30-11:00 a.m. PT)

Ponatinib

Outcome by Mutation Status and Line of Treatment in OPTIC, a Dose-Ranging Study of 3 Starting Doses of Ponatinib in Patients with CP-CML2 (Abstract #48, Session: 632. Chronic Myeloid Leukemia: Therapy—Building The Future CML. Saturday, December 5, 7:30-9:00 a.m. PT)

Efficacy and Safety of Ponatinib (PON) in Patients with Chronic-Phase Chronic Myeloid Leukemia (CP-CML) Who Failed One or More Second-Generation (2G) Tyrosine Kinase Inhibitors (TKIs): Analyses Based on PACE and OPTIC 2 (Abstract #647, Session: 632. Chronic Myeloid Leukemia: Therapy: CML: New and Beyond. Monday, December 7, 11:30 a.m.-1:00 p.m. PT)

Itacitinib

A Single-Arm, Open-Label, Phase 1 Study of Itacitinib (ITA) with Calcineurin Inhibitor (CNI)-Based Interventions for Prophylaxis of Graft-Versus-Host Disease (GVHD; GRAVITAS-119) (Abstract #356, Session: 722. Clinical Allogeneic Transplantation; Acute and Chronic GvHD, Immune Reconstitution: Phase I and II Trials. Sunday, December 6, 9:30-11:00 a.m. PT)

Poster Presentations
All accepted posters in Poster I and Poster II sessions are available from 7:00 a.m.-3:30 p.m. PT on Saturday and Sunday, December 5 and 6. All accepted posters in the Poster III sessions are available from 7:00 a.m.-3:00 p.m. PT on Monday, December 7.

Ruxolitinib: Graft-Versus-Host Disease (GVHD)

Biomarker Analysis in Patients with Steroid-Refractory Acute Graft-Versus-Host Disease (aGVHD) Treated with Ruxolitinib (RUX) or Best Available Therapy (BAT) in the Randomized, Phase 3 REACH2 Study 1 (Abstract #1519, Session: 732. Clinical Allogeneic Transplantation: Results: Poster I. Saturday, December 5)

Ruxolitinib, a JAK1/2 Inhibitor, is Efficacious in a Novel Humanized GVHD Model Characterized by Enhanced NK, NK-T and T-Cell Engraftment (Abstract #1422, Session: 701. Experimental Transplantation: Basic Biology, Pre-Clinical Models: Poster I. Saturday, December 5)

Safety Analysis of Patients Who Received Ruxolitinib for the Treatment of Steroid-Refractory Chronic Graft-Versus-Host Disease in an Expanded Access Program (Abstract #1488, Session: 722. Clinical Allogeneic Transplantation: Acute and Chronic GVHD, Immune Reconstitution: Poster I. Saturday, December 5)

Safety Analysis of Ruxolitinib (RUX) vs. Best Available Therapy (BAT) in Patients (pts) with Steroid-Refractory (SR) Acute Graft-Versus-Host Disease (aGVHD) in the Randomized Phase 3 REACH2 Study 1 (Abstract #2440, Session: 732. Clinical Allogeneic Transplantation: Results: Poster II. Sunday, December 6)

Ruxolitinib: Myeloproliferative Neoplasms (MPN)

An International Multicentric Observational Study on the Use of Ruxolitinib in Patients with Polycythemia Vera Resistant or Intolerant to Hydroxyurea: Results from Interim Analysis 1 (Abstract #1256, Session: 634. Myeloproliferative Syndromes: Clinical: Poster I. Saturday, December 5)

Clinical Characteristics and Treatment Patterns by Risk Stratification in Patients with Essential Thrombocythemia: An Analysis of the MOST Study (Abstract #1258, Session: 634. Myeloproliferative Syndromes: Clinical: Poster I. Saturday, December 5)

The Final Analysis of EXPAND: A Phase 1b, Open-Label, Dose-Finding Study of Ruxolitinib (RUX) in Patients (pts) with Myelofibrosis (MF) and Low Platelet (PLT) Count (50 × 109/L to <
100 × 109/L) at Baseline 1 (Abstract #1252, Session: 634. Myeloproliferative Syndromes: Clinical: Poster I. Saturday, December 5)


Clinical & Economic Implications of Hydroxyurea Intolerance in Polycythemia Vera in Routine Clinical Practice 1 (Abstract #2477, Session: 901. Health Services Research-Non-Malignant Conditions: Poster II. Sunday, December 6)

Interactions of Key Hematological Parameters with Red Cell Distribution Width (RDW) are Associated with Incidence of Thromboembolic Events (TEs) in Polycythemia Vera (PV) Patients: A Machine Learning Study (PV-AIM) 1 (Abstract #2991, Session: 634. Myeloproliferative Syndromes: Clinical: Poster III. Monday, December 7)

Long-Term Effect of Ruxolitinib (RUX) in Inadequately Controlled Polycythemia Vera (PV) Without Splenomegaly: 5-Year Results from the Phase 3 Response-2 Study 1 (Abstract #2987, Session: 624. Hodgkin Lymphoma and T/NK Cell Lymphoma—Clinical Studies: Poster III. Monday, December 7)


Parsaclisib
Phase 2 Study Evaluating the Efficacy and Safety of Parsaclisib in Patients with Relapsed or Refractory Mantle Cell Lymphoma Not Previously Treated with a BTK Inhibitor (CITADEL-205) (Abstract #1121, Session: 623. Mantle Cell, Follicular, and Other Indolent B-Cell Lymphoma—Clinical Studies: Poster I. Saturday, December 5)

Phase 2 Study Evaluating the Efficacy and Safety of Parsaclisib in Patients with Relapsed or Refractory Mantle Cell Lymphoma Previously Treated with Ibrutinib (CITADEL-205) (Abstract #2044, Session: 623. Mantle Cell, Follicular, and Other Indolent B-Cell Lymphoma—Clinical Studies: Poster II. Sunday, December 6)

Phase 2 Study Evaluating the Efficacy and Safety of Parsaclisib in Patients with Relapsed or Refractory Follicular Lymphoma (CITADEL-203) (Abstract #2935, Session: 623. Mantle Cell, Follicular, and Other Indolent B-Cell Lymphoma—Clinical Studies: Poster III. Monday, December 7)

Ponatinib

Ponatinib Versus Imatinib with Reduced-Intensity Chemotherapy in Patients with Newly Diagnosed Philadelphia Chromosome–Positive (Ph+) Acute Lymphoblastic Leukemia (ALL): PhALLCON Study 2 (Abstract #1026, Session: 615. Acute Myeloid Leukemia: Commercially Available Therapy, excluding Transplantation: Poster I. Saturday, December 5)

A Phase 1/2 Study to Evaluate the Safety and Efficacy of Ponatinib with Chemotherapy in Pediatric Patients with Philadelphia Chromosome-Positive (Ph+) Acute Lymphoblastic Leukemia (ALL) 2 (Abstract #2842, Session: 614. Acute Lymphoblastic Leukemia: Therapy, excluding Transplantation: Poster III. Monday, December 7)


Tafasitamab

The Combination of Tafasitamab and Rituximab Increases Cytotoxicity Against Lymphoma Cells In Vitro3 (Abstract #2095, Session: 625. Lymphoma: Pre-Clinical-Chemotherapy and Biologic Agents: Poster II. Sunday, December 6)
A Phase 1b, Open-label, Randomized Study to Assess Safety and Preliminary Efficacy of Tafasitamab (MOR208) or Tafasitamab + Lenalidomide in Addition to R-CHOP in Patients with Newly Diagnosed Diffuse Large B-Cell Lymphoma: Analysis of the Safety Run-In Phase

(Long-Term Subgroup Analyses from L-MIND, a Phase 2 Study of Tafasitamab (MOR208) Combined with Lenalidomide in Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma)

Blockade of the CD47/SIRPα Checkpoint Potentiates the Anti-Tumor Efficacy of Tafasitamab

INCB057643

A Phase 1 Study of INCB057643 Monotherapy in Patients with Relapsed or Refractory Myelofibrosis (INCB57643-103)

INCB000928

A Phase 1/2 Study of INCB000928 as Monotherapy or in Combination with Ruxolitinib in Patients with Anemia Due to Myelofibrosis (INCB00928-104)

Characterization of INCB000928, a Potent and Selective ALK2 Inhibitor for the Treatment of Anemia

Full session details and listings for oral presentations and poster sessions are available in the ASH 2020 program: https://ash.confex.com/ash/2020/webprogram/start.html

About Jakafi® (ruxolitinib)

Jakafi is a first-in-class JAK1/JAK2 inhibitor approved by the U.S. FDA for the 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 and for the treatment of steroid-refractory acute GVHD 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

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.

Iclusig is approved in the U.S., EU, UK, Australia, Switzerland, Israel and Canada. 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.

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).

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 diffuse large B-cell lymphoma (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 January 2020, MorphoSys and Incyte entered into a collaboration and licensing agreement to further develop and commercialize tafasitamab globally. Monjuvi is being co-commercialized by Incyte and MorphoSys in the United States. Incyte has exclusive commercialization rights outside the United States.
A marketing authorization application (MAA) seeking the approval of tafasitamab in combination with lenalidomide in the EU has been validated by the European Medicines Agency (EMA) and is currently under review for the treatment of adult patients with relapsed or refractory DLBCL, including DLBCL arising from low grade lymphoma, who are not candidates for ASCT.

Tafasitamab is being clinically investigated as a therapeutic option in B-cell malignancies in a number of ongoing combination trials.

Monjuvi® is a registered trademark of MorphoSys AG.
XmAb® is a registered trademark of Xencor, Inc.

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 oncology development portfolio, alone and in conjunction with its collaboration partners; whether or when any such compounds will be approved or commercially available for use in humans anywhere in the world or will improve the lives of patients; and the likelihood of continued approval of Monjuvi in DLBCL in the U.S. and whether it will also be approved by the EMA, 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; determinations made by the FDA or the EMA; the efficacy or safety of the Company's products; the acceptance of the Company's products and the products of the Company's collaboration partners in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; greater than expected expenses; expenses relating to litigation or strategic activities; and other risks detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, including its Form 10-Q for the quarter ended September 30, 2020. The Company disclaims any intent or obligation to update these forward-looking statements.
1 Novartis-sponsored abstract.
2 Takeda-sponsored abstract.
3 MorphoSys-sponsored abstract.

View source version on businesswire.com: https://www.businesswire.com/news/home/20201104005702/en/

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

Nupur Patel, PharmD
+1 302 498 5822
npatel@incyte.com

Investors
Michael Booth, DPhil
+1 302 498 5914
mbooth@incyte.com

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

Source: Incyte