

## Multiple Abstracts Highlighting Data from Incyte's Targeted Therapy Portfolio Accepted for Presentation at the 60th Annual ASH Meeting

November 1, 2018

*Results of REACH1 trial evaluating ruxolitinib (Jakafi®) in patients with steroid-refractory acute graft-versus-host disease (GVHD) accepted as an oral presentation*

WILMINGTON, Del.--(BUSINESS WIRE)--Nov. 1, 2018-- Incyte (Nasdaq:INCY) announces that multiple abstracts, including data from its clinical development programs for ruxolitinib (Jakafi®), pemigatinib and INCB50465 will be presented at the upcoming American Society of Hematology (ASH) Annual Meeting 2018 in San Diego, California, from December 1-4, 2018.

Key data presented at ASH 2018 will include results from the pivotal REACH1 trial evaluating ruxolitinib in combination with corticosteroids for the treatment of patients with acute graft-versus-host disease (GVHD) who have had an inadequate response to corticosteroids, which have been accepted for oral presentation. Additionally, new data from the Phase 2 study evaluating INCB50465 in combination with ruxolitinib in patients with myelofibrosis (MF) and initial data from the Phase 2 fight-203 study evaluating pemigatinib in patients with myeloproliferative neoplasms (MPNs) with activating FGFR1 translocations have been accepted for oral presentation.

"We are looking forward to highlighting our later-stage, targeted therapy portfolio at this year's ASH Annual Meeting," said Steven Stein, M.D., Chief Medical Officer, Incyte. "Specifically, we are pleased to present results from our REACH1 study, which formed the basis of our supplemental new drug application for ruxolitinib as a treatment for acute GVHD that is currently under Priority Review by the FDA, and new data from our INCB50465 and pemigatinib clinical development programs, which further underscore our leadership in MPNs."

Key abstract presentations include:

### **Ruxolitinib (Jakafi)**

#### **Oral Presentations**

***Safety and Efficacy of Combined Ruxolitinib and Thalidomide in Patients with Myelofibrosis: Initial Results of a Phase 2 Study (Abstract #354)***

- Sunday, December 2, 2018, 9:30-11:00 a.m., Manchester Grand Hyatt, Seaport Ballroom F, Oral Session 634, Myeloproliferative Syndromes: Clinical: Addressing Areas of Unmet Need in Prognostic Assessments and Therapy for MPNs

***Results from REACH1, a Single-arm Phase 2 Study of Ruxolitinib in Combination with Corticosteroids for the Treatment of Steroid-Refractory Acute Graft-vs-Host Disease (Abstract #601)***

- Monday, December 3, 2018, 7:00-8:30 a.m., Manchester Grand Hyatt, Grand Hall A, Oral Session 722, Clinical Allogeneic Transplantation: Acute and Chronic GVHD

***A Phase 2 Study of Ruxolitinib with Chemotherapy in Children with Philadelphia Chromosome-like Acute Lymphoblastic Leukemia (INCB18424-269/AALL1521): Dose-Finding Results from the Part 1 Safety Phase (Abstract #555)***

- Monday, December 3, 2018, 7:00-8:30 a.m., San Diego Convention Center, Ballroom 20A, Oral Session 614, Acute Lymphoblastic Leukemia: Therapy, excluding Transplantation: Targeted Therapy in ALL: Immunotherapy and Beyond

***RUXOPEG, a Multi-Center Bayesian Phase 1/2 Adaptive Randomized Trial of the Combination of Ruxolitinib and Pegylated Interferon Alpha 2a in Patients with Myeloproliferative Neoplasms-Associated Myelofibrosis\* (Abstract #581)***

- Monday, December 3, 2018, 7:00-8:30 a.m., Manchester Grand Hyatt, Grand Hall D, Oral Session 634, Myeloproliferative Syndromes: Clinical: Interferon Therapy and Mutational Analysis in the MPNs

#### **Poster Sessions**

***Updated Results from An Open-Label, Multicenter, Expanded Treatment Protocol (ETP) Phase (Ph) 3b Study Of Ruxolitinib (Rux) In Patients (Pts) With Polycythemia Vera (PV) Who Are Hydroxyurea (HU) Resistant Or Intolerant And For Whom No Alternative Treatments Are Available (Abstract #1774)***

- Saturday, December 1, 2018, 6:15-8:15 p.m., San Diego Convention Center, Hall GH, Poster Session 634, Myeloproliferative Syndromes: Clinical: Poster I

***Characteristics Associated with Hydroxyurea Treatment Change in Patients with Polycythemia Vera: An Analysis from the REVEAL Study (Abstract #1770)***

- Saturday, December 1, 2018, 6:15-8:15 p.m., San Diego Convention Center, Hall GH, Poster Session 634,

***Real-World Risk Assessment and Treatment of Patients with Myelofibrosis at Community Oncology Practices in the United States***(Abstract #1765)

- Saturday, December 1, 2018, 6:15-8:15 p.m., San Diego Convention Center, Hall GH, Poster Session 634, Myeloproliferative Syndromes: Clinical: Poster I

***Impact of Myeloproliferative Neoplasms on Patients' Employment and Income: Findings from the Living with MPN Survey***(Abstract #2250)

- Saturday, December 1, 2018, 6:15-8:15 p.m., San Diego Convention Center, Hall GH, Poster Session 902, Health Services Research – Malignant Diseases: Poster I

***Elevated White Blood Cell levels and Thrombotic Events in Patients with Polycythemia Vera: A Real-World Analysis of Veterans Health Administration Data*** (Abstract #1758)

- Saturday, December 1, 2018, 6:15-8:15 p.m., San Diego Convention Center, Hall GH, Poster Session 634, Myeloproliferative Syndromes: Clinical: Poster I

***Correlation between MPN-SAF TSS and EORTC QLQ-C30 Scores in Patients with PV: Data from the REVEAL Study*** (Abstract #2259)

- Saturday, December 1, 2018, 6:15-8:15 p.m., San Diego Convention Center, Hall GH, Poster Session 902, Health Services Research – Malignant Diseases: Poster I

***Long-term Efficacy and Safety (5 Years) in RESPONSE, a Phase 3 Study Comparing Ruxolitinib (rux) With Best Available Therapy (BAT) in Hydroxyurea (HU)-resistant/intolerant Patients (pts) With Polycythemia Vera (PV)***

- Saturday, December 1, 2018, 6:15-8:15 p.m., San Diego Convention Center, Hall GH, Poster Session 634, Myeloproliferative Syndromes: Clinical: Poster I

***Ruxolitinib for the Treatment of Inadequately Controlled Polycythemia Vera Without Splenomegaly: 156-Week Follow-Up From the Phase 3 RESPONSE-2 Study*** (Abstract #1754)

- Saturday, December 1, 2018, 6:15-8:15 p.m., San Diego Convention Center, Hall GH, Poster Session 634, Myeloproliferative Syndromes: Clinical: Poster I

***Disease and Clinical Characteristics of Patients with Essential Thrombocythemia Enrolled in the MOST Study*** (Abstract #4306)

- Monday, December 3, 2018, 6:00-8:00 p.m., San Diego Convention Center, Hall GH, Poster Session 634, Myeloproliferative Syndromes: Clinical: Poster III

***Disease Characteristics of Minority Patient Populations with Polycythemia Vera: An Analysis from the REVEAL Study*** (Abstract #4735)

- Monday, December 3, 2018, 6:00-8:00 p.m., San Diego Convention Center, Hall GH, Poster Session 902, Health Services Research – Malignant Diseases: Poster III

***Real-World Management of Myelofibrosis with Ruxolitinib: Initial Analysis of an Italian Observational Study (ROMEI)*** (Abstract #4312)

- Monday, December 3, 2018, 6:00-8:00 p.m., San Diego Convention Center, Hall GH, Poster Session 634, Myeloproliferative Syndromes: Clinical: Poster III

***Impact of Myeloproliferative Neoplasms (MPNs) on Health-Related Quality of Life (HRQOL) and Medical Resource Utilization: Results from the MERGE Registry*** (Abstract #4311)

- Monday, December 3, 2018, 6:00-8:00 p.m., San Diego Convention Center, Hall GH, Poster Session 634: Myeloproliferative Syndromes: Clinical: Poster III

**INCB50465 (PI3Kδ)**

**Oral Presentation**

***A Phase 2 Study of the Safety and Efficacy of INCB050465, a Selective PI3Kδ Inhibitor, in Combination with Ruxolitinib in Patients with Myelofibrosis*** (Abstract #353)

- Sunday, December 2, 2018, 9:30-11:00 a.m., Manchester Grand Hyatt, Seaport Ballroom F, Oral Session 634, Myeloproliferative Syndromes: Clinical: Addressing Areas of Unmet Need in Prognostic Assessments and Therapy for MPNs

**Poster Session**

**Cell-of-Origin Subtype Prediction of Diffuse Large B-cell Lymphoma Using Gene Expression and Proteomic Data** (Abstract #1712)

- Saturday, December 1, 2018, 6:15-8:15 p.m., San Diego Convention Center, Hall GH, Poster Session 627, Aggressive Lymphoma (Diffuse Large B-Cell and Other Aggressive B-Cell Non-Hodgkin Lymphomas)—Results from Retrospective/Observational Studies: Poster I

**Pemigatinib (INCB054828)**

**Oral Presentation**

***Interim Results from fight-203, a Phase 2, Open-Label, Multicenter Study Evaluating the Efficacy and Safety of Pemigatinib (INCB054828) in Patients with Myeloid/Lymphoid Neoplasms with Rearrangement of Fibroblast Growth Factor Receptor 1 (FGFR1)*** (Abstract #690)

- Monday, December 3, 2018, 10:30-12:00 p.m., Manchester Grand Hyatt, Grand Hall A, Oral Session 634, Myeloproliferative Syndromes: Clinical: Emerging Therapies and Prognostic Scoring in Myelofibrosis and Other MPNs

**Itacitinib**

***Plasma Biomarker Association with Response in Acute GVHD Subjects Treated With the Combination of Itacitinib and Corticosteroids in a Phase 1 Clinical Trial*** (Abstract #4559)

- Monday, December 3, 2018, 6:00-8:00 p.m., San Diego Convention Center, Hall GH, Poster Session 722, Clinical Allogeneic Transplantation: Acute and Chronic GVHD, Immune Reconstitution: Poster III

**Ponatinib**

***Efficacy and Safety of Ponatinib in CML and Ph+ ALL Patients in Real World Clinical Practice – Data from a Belgian Registry*** (Abstract #1744)

- Saturday, December 1, 2018, 6:15-8:15 p.m., San Diego Convention Center, Hall GH, Poster Session 632, Chronic Myeloid Leukemia: Therapy: Poster I

**Preclinical**

***The Persistent Survival of MPN Cells to JAK2 Inhibition is Dependent on SHP2 Activity, Which May Provide a Therapeutic Target to Enhance Current Anti-MPN Therapies*** (Abstract #3064)

- Sunday, December 2, 2018, 6:00-8:00 p.m., San Diego Convention Center, Hall GH, Poster Session 635, Myeloproliferative Syndromes: Basic Science: Poster II

***Itacitinib, a JAK1 Selective Inhibitor Preserves Graft-versus-Leukemia (GVL), Enhances Survival and is Highly Efficacious in a MHC-mismatched Mouse Model of Acute GvHD*** (Abstract #4522)

- Monday, December 3, 2018, 6:00-8:00 p.m., San Diego Convention Center, Hall GH, Poster Session 701, Experimental Transplantation: Basic Biology, Pre-Clinical Models Poster III

***Ruxolitinib, a JAK1/JAK2 Selective Inhibitor is Highly Efficacious in Corticosteroid Untreated and Refractory MHC-mismatched Mouse Model of Acute GvHD*** (Abstract 4523)

- Monday, December 3, 2018, 6:00-8:00 p.m., San Diego Convention Center, Hall GH, Poster Session 701, Experimental Transplantation: Basic Biology, Pre-Clinical Models: Poster III

Full session details and data presentation listings for ASH 2018 can be found at: <https://ash.confex.com/ash/2018/webprogram/start.html>.

**About Jakafi®(ruxolitinib)**

Jakafi is a first-in-class JAK1/JAK2 inhibitor approved by the U.S. Food and Drug Administration for treatment of people with polycythemia vera (PV) who have had an inadequate response to or are intolerant of hydroxyurea.

Jakafi is also indicated for treatment of people with intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF, and post-essential thrombocythemia MF.

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. Ruxolitinib is also being evaluated in patients with acute and chronic GVHD who have an inadequate response to corticosteroids in the REACH2 and REACH3 clinical studies, respectively. It is expected that these two pivotal studies will complete in 2019, and could support additional regulatory submissions, in the U.S. by Incyte and ex-U.S. by Novartis, in 2020.

**Important Safety Information**

**Jakafi can cause serious side effects, including:**

**Low blood counts:** Jakafi® (ruxolitinib) may cause your platelet, red blood cell, or white blood cell counts to be lowered. If you develop bleeding, stop

taking Jakafi and call your healthcare provider. Your healthcare provider will perform blood tests to check your blood counts before you start Jakafi and regularly during your treatment. Your healthcare provider may change your dose of Jakafi or stop your treatment based on the results of your blood tests. Tell your healthcare provider right away if you develop or have worsening symptoms such as unusual bleeding, bruising, tiredness, shortness of breath, or a fever.

**Infection:** You may be at risk for developing a serious infection during treatment with Jakafi. Tell your healthcare provider if you develop any of the following symptoms of infection: chills, nausea, vomiting, aches, weakness, fever, painful skin rash or blisters.

**Skin cancers:** Some people who take Jakafi have developed certain types of non-melanoma skin cancers. Tell your healthcare provider if you develop any new or changing skin lesions.

**Increases in Cholesterol:** You may have changes in your blood cholesterol levels. Your healthcare provider will do blood tests to check your cholesterol levels during your treatment with Jakafi.

**The most common side effects of Jakafi include:** low platelet count, low red blood cell counts, bruising, dizziness, headache.

These are not all the possible side effects of Jakafi. Ask your pharmacist or healthcare provider for more information. Tell your healthcare provider about any side effect that bothers you or that does not go away.

**Before taking Jakafi, tell your healthcare provider about:** all the medications, vitamins, and herbal supplements you are taking and all your medical conditions, including if you have an infection, have or had tuberculosis (TB), or have been in close contact with someone who has TB, have or had hepatitis B, have or had liver or kidney problems, are on dialysis, had skin cancer or have any other medical condition. Take Jakafi exactly as your healthcare provider tells you. Do not change or stop taking Jakafi without first talking to your healthcare provider. Do not drink grapefruit juice while on Jakafi.

Women should not take Jakafi while pregnant or planning to become pregnant, or if breast-feeding.

**Full Prescribing Information, which includes a more complete discussion of the risks associated with Jakafi, is available at [www.jakafi.com](http://www.jakafi.com).**

#### **About Incyte**

Incyte Corporation is a Wilmington, Delaware-based biopharmaceutical company focused on the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit the Company's website at [www.incyte.com](http://www.incyte.com).

Follow @Incyte on Twitter at <https://twitter.com/Incyte>.

#### **Forward-Looking Statements**

Except for the historical information set forth herein, the matters set forth in this press release, including statements regarding the Company's development pipeline and its presentation plans for the upcoming ASH annual meeting, 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 and the risks related to the efficacy or safety of the Company's development pipeline, the results of further research and development, the high degree of risk and uncertainty associated with drug development, clinical trials and regulatory approval processes, other market or economic factors and competitive and technological advances; 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, 2018. Incyte disclaims any intent or obligation to update these forward-looking statements.

\* Ex-U.S. Investigator Initiated Trials (IITs) are funded by Novartis.

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