

Incyte to Present Diversified Development Portfolio and Opportunities for Accelerated Growth at 2018 Investor and Analyst Event

June 21, 2018

- *Five late-stage oncology product candidates being developed in 15 different indications have the potential to significantly accelerate near-term revenue growth*
- *Pivotal REACH1 study of Jakafi® (ruxolitinib) in steroid-refractory acute GVHD met primary endpoint; sNDA submission expected in the third quarter of 2018*
- *Development programs for PD-1 antagonist and JAK1, FGFR and PI3Kδ inhibitors progressing as planned, with the first NDA submission for INCB54828 (FGFR) in cholangiocarcinoma expected in 2019*
- *Inflammation/autoimmunity portfolio highlighted by success of randomized study of topical ruxolitinib in mild-to-moderate atopic dermatitis*

WILMINGTON, Del.--(BUSINESS WIRE)--Jun. 21, 2018-- Incyte Corporation (Nasdaq:INCY) will host an investor and analyst event in New York City today to provide a comprehensive update on the Company's growth opportunities and late-stage development portfolio.

"The presentations today are intended to highlight our diversified development portfolio and its potential to accelerate our top-line growth in the near term," said Hervé Hoppenot, Chief Executive Officer, Incyte. "The success of the REACH1 study of Jakafi in steroid-refractory acute graft-versus-host disease (GVHD) announced earlier today is excellent news for patients, and also further reinforces the potential of JAK inhibition in GVHD and our development strategy to address this devastating disease. We will also discuss our strategies to extend our leadership in the treatment of myeloproliferative neoplasms, as well as present recent data emerging from our research and development programs for our FGFR inhibitor in cholangiocarcinoma and bladder cancer, and positive results from a randomized Phase 2 study of topical ruxolitinib in patients with atopic dermatitis."

A live webcast of the 2018 investor and analyst event will begin at 1:00 p.m. EDT. The live webcast and slide deck will be available via the Events & Presentations page under the Investor section of Incyte's website at www.incyte.com. A replay will be available following the event.

Key Highlights

COMFORT – Extending leadership in myeloproliferative neoplasms (MPNs)

Jakafi® (ruxolitinib) has transformed the lives of thousands of patients with MPNs since it was launched in the U.S. in 2011. However, there remain certain patients with MPNs that may have an inadequate response to, or are unable to tolerate, Jakafi monotherapy at its currently approved doses. These patients represent an R&D priority for Incyte—clinical trials are ongoing to evaluate combination strategies with Jakafi and Incyte molecules, as are discovery efforts to identify de novo drug targets that may become future therapeutic options that further improve outcomes and control the burden of disease for patients with MPNs.

REACH – Jakafi (ruxolitinib, JAK1/JAK2) in steroid-refractory GVHD

As [announced earlier today](#), the REACH1 pivotal trial of ruxolitinib in combination with corticosteroids for the treatment of patients with steroid-refractory acute GVHD met its primary endpoint. Based on these data, Incyte plans to file a supplemental New Drug Application (sNDA) for the approval of ruxolitinib for the treatment of steroid-refractory acute GVHD with the U.S. Food and Drug Administration (FDA) during the third quarter of 2018.

REACH2, the Novartis-sponsored Phase 3 trial in steroid-refractory acute GVHD, and REACH3, the Phase 3 trial in steroid-refractory chronic GVHD that is co-sponsored by Incyte and Novartis, are both underway; data are expected in 2019.

GRAVITAS – Itacitinib (JAK1) in steroid-naïve GVHD

Itacitinib is being developed for the treatment of patients with treatment-naïve GVHD. The GRAVITAS-301 study in newly-diagnosed acute GVHD is underway, with data expected in 2019. Additionally, a pivotal trial in newly-diagnosed chronic GVHD is being initiated, and a proof-of-concept trial in the prophylactic setting is already recruiting patients.

Incyte has global rights for the development and commercialization of itacitinib.

FIGHT – INCB54828 (FGFR) in cholangiocarcinoma and bladder cancer

Initial data from the FIGHT-202 trial evaluating INCB54828 in patients with advanced cholangiocarcinoma are encouraging; showing promising efficacy in patients with FGFR2 translocations. Incyte expects to submit a NDA for INCB54828 as a treatment for patients with advanced cholangiocarcinoma in 2019.

Additionally, initial data from the FIGHT-201 trial of INCB54828 in patients with advanced bladder cancer with FGFR3 mutations or fusions are also encouraging, and a continuous dosing cohort has been added to this ongoing study.

Incyte has global rights for the development and commercialization of INCB54828.

CITADEL – INCB50465 (PI3Kδ) in non-Hodgkin lymphoma (NHL)

INCB50465 is being developed as a treatment for different forms of NHL. Recruitment of patients with follicular, marginal zone and mantle cell lymphoma into monotherapy trials within the CITADEL program is ongoing, with initial data expected in 2019. Evaluation of combination approaches, adding INCB50465 to standards of care in NHL, is also underway. Initial efficacy data from the trial in patients with diffuse large B cell lymphoma (DLBCL; CITADEL-202) did not meet defined response rate criteria, and this study will not be extended.

Incyte has global rights for the development and commercialization of INCB50465.

POD1UM – INCMGA0012 (PD-1) in solid tumors

The POD1UM clinical development program for INCMGA0012 will include combination studies with internal candidates and monotherapy, single-arm, registration-directed studies in Merkel cell carcinoma, anal cancer and microsatellite instability (MSI)-high endometrial cancer, as well as other indications where PD-1 axis blockade is standard of care. Recruitment for these studies is expected to begin later this year, and initial data are expected in 2020.

Incyte licensed INCMGA0012 from MacroGenics, and has global rights for its development and commercialization.

TRuE-Derm – Topical ruxolitinib (JAK1/JAK2) in dermatology

The recently completed randomized trial of topical ruxolitinib in patients with mild-to-moderate atopic dermatitis showed a significant benefit over vehicle control; these data have been accepted for oral presentation at the 27th European Academy of Dermatology and Venerology Congress, September 12-16, 2018 in Paris, France, and preparations are already underway for a global, pivotal Phase 3 program.

Incyte has global rights for the development and commercialization of topical ruxolitinib.

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.

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

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 U.S. and by Novartis as Jakavi® (ruxolitinib) outside the U.S. Jakafi is a registered trademark of Incyte Corporation. Jakavi is a registered trademark of Novartis AG in countries outside the U.S.

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.

Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this presentation contain predictions, estimates and other forward-looking statements, including without limitation statements regarding: our ability to capitalize on potential opportunities for additional growth, grow our top-line revenue quickly or at all and develop any of the compounds in our development portfolio successfully; the expectation that top-line growth could be accelerated by future launches and the anticipated and possible timing of future NDAs and sNDAs; our plans to extend our leadership in MPNs; our expectations for revenue acceleration from multiple products and in new indications and near-term product launches; our plans for development and clinical trials of ruxolitinib in additional indications and for our other product candidates, including the timing of clinical development and availability and submission of data, and our expectations regarding the pivotal nature of ongoing trials; and our expectations that we can exploit our existing expertise and develop new products and product candidates to address new and additional indications. These forward-looking statements are based on our current expectations and are subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: the effects of competition; 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; our dependence on our relationships with our collaboration partners; the efficacy or safety of our products and the products of our collaboration partners; the acceptance of our products and the products of our collaboration partners in the marketplace; our ability to leverage our field teams; sales, marketing, manufacturing and distribution requirements; our ability to identify and exploit opportunities for our assets; greater than expected expenses; expenses relating to litigation or strategic activities; and other risks detailed from time to time in our reports filed with the Securities and Exchange Commission, including our Form 10-Q for the quarter ended March 31, 2018. We disclaim any intent or obligation to update these forward-looking statements.



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