

# New Data for Multiple Incyte Cancer Programs to Be Presented at the 2014 American Society of Clinical Oncology (ASCO) Meeting

May 28, 2014

- Results from RECAP, a Phase II trial of ruxolitinib in metastatic pancreatic cancer and proof-of-concept for the role of a JAK1/JAK2 inhibitor in treating onco-inflammation
- Preliminary results from an ongoing Phase I/II trial of INCB24360, a novel immuno-oncology compound, in combination with ipilimumab in metastatic melanoma
- Results from RESPONSE, a pivotal Phase III trial of ruxolitinib in uncontrolled polycythemia vera
- Incyte to host investor webcasts featuring key results on Monday, June 2, 2014, at 6:45 p.m. CDT and Tuesday, June 3, 2014, at 1:15 p.m. CDT

WILMINGTON, Del.--(BUSINESS WIRE)--May 28, 2014-- Incyte Corporation (Nasdaq: INCY) today announced that new data from its lead cancer programs focused on onco-inflammation, immuno-oncology and myeloproliferative neoplasms will be presented at the 50<sup>th</sup> Annual Meeting of the American Society of Clinical Oncology (ASCO) being held from May 30 to June 3, 2014, in Chicago.

Data to be presented on June 2 include full results from RECAP, the Phase II trial of ruxolitinib in combination with capecitabine in metastatic pancreatic cancer. This proof-of-concept trial was designed to evaluate the benefits of targeting local and systemic inflammation that adversely impact patient outcomes in pancreatic cancer and many other cancers. Topline results from RECAP, announced in August 2013, showed an overall survival benefit in a pre-specified subgroup analysis of patients. This subgroup consisted of patients with increased levels of serum C-reactive protein (CRP), a well-characterized and readily measurable marker of systemic inflammation.

Also being presented on June 2 are preliminary findings from a Phase I/II study of Incyte's IDO1 inhibitor, INCB24360, in combination with ipilimumab in patients with metastatic melanoma. This trial was designed to examine potential synergy with other cancer immunotherapies and lay the groundwork for future potential combinations with INCB24360.

On June 3, full results will be presented from the pivotal Phase III RESPONSE trial of ruxolitinib in patients with uncontrolled polycythemia vera (PV), building upon Incyte's efforts to improve the lives of patients with myeloproliferative neoplasms. RESPONSE is the first Phase III study to evaluate a JAK inhibitor as a treatment for patients with PV. In March 2014, Incyte announced that the RESPONSE trial met its primary endpoint.

"These three studies showcase several of the innovative therapies that comprise Incyte's growing oncology pipeline, including first-in-class compounds in the areas of onco-inflammation and immuno-oncology, which we believe have the potential to transform the way cancer is treated," stated Hervé Hoppenot, President and Chief Executive Officer, Incyte. "We look forward to sharing the results of these studies in a prestigious oncology forum such as ASCO."

## **Presentation Details**

• Onco-Inflammation: Results from the RECAP Trial (Metastatic Pancreatic Cancer)

Hurwitz H. W, Uppal N, Wagner SA, et al. A randomized double-blind phase II study of ruxolitinib or placebo with capecitabine as second-line therapy in patients with metastatic pancreatic cancer.

Abstract #4000: Oral Abstract Session: Gastrointestinal (Non-colorectal) Cancer.

June 2, 2014, 1:15 - 4:15 p.m. CDT.

• Immuno-Oncology: INCB24360 in Metastatic Melanoma

Gibney GT, Hamid O, Gangadhar TC, et al. Preliminary results from a phase I/II study of INCB24360 combined with ipilimumab in patients with melanoma.

Abstract #3010: Poster Highlights Session: Developmental Therapeutics – Immunotherapy.

June 2, 2014, 1:15 - 6 p.m. CDT with discussion from 4:45 to 6 p.m. CDT.

• MPNs: Results from the RESPONSE Trial (Polycythemia Vera)

Verstovsek S, Kiladjian JJ, Griesshammer M, et al. Results of a prospective, randomized, open-label Phase III study of ruxolitinib in polycythemia vera patients resistant to or intolerant of hydroxyruea: the RESPONSE trial.

Abstract #7026: Oral Abstract Session: Leukemia, Myelodysplasia and Transplantation

June 3, 2014, 9:45 a.m. - 12:45 p.m. CDT.

#### **About the Webcasts**

Incyte will host investor meetings to discuss the data being presented at ASCO. The two investor presentations will be webcast live on Monday, June 2, 2014, at 6:45 p.m. CDT and Tuesday, June 3, 2014, at 1:15 p.m. CDT. Both presentations can be accessed at <a href="www.incyte.com">www.incyte.com</a> under Investor Relations, Events and Webcasts. A replay of the event will be available for 60 days.

#### **About Ruxolitinib**

Ruxolitinib is an oral, selective inhibitor of Janus kinases 1 and 2 (JAK1 and JAK2). In the United States, ruxolitinib, brand name Jakafi<sup>®</sup>, is indicated for treatment of patients 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<sup>®</sup> (ruxolitinib) outside the United States.

#### **Important Safety Information**

## Jakafi can cause serious side effects including:

Low blood counts: Jakafi 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 experience unusual bleeding, bruising, fatigue, shortness of breath, or a fever.

**Infection**: You may be at risk for developing a serious infection while taking Jakafi. Tell your healthcare provider if you develop symptoms such as chills, nausea, vomiting, aches, weakness, fever, or painful skin rash or blisters.

## The most common side effects of Jakafi include dizziness and headache.

These are not all the possible side effects of Jakafi. Ask your healthcare provider or pharmacist 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 liver or kidney problems, are on dialysis, or have any other medical condition. Do not drink grapefruit juice while taking Jakafi.

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

Please see the Full Prescribing Information available at <a href="www.jakafi.com">www.jakafi.com</a>, which includes a more complete discussion of the risks associated with Jakafi.

# **About Incyte**

Incyte Corporation is a Wilmington, Delaware-based biopharmaceutical company focused on the discovery, development and commercialization of proprietary small molecule drugs, primarily in oncology. For additional information on Incyte, please visit the Company's website at <a href="https://www.incyte.com">www.incyte.com</a>.

## **Forward-Looking Statements**

Except for the historical information set forth herein, the matters set forth in this press release, including without limitation statements with respect to the potential efficacy, safety and therapeutic value of Incyte's pipeline compounds and their potential to transform the way cancer is treated, contain predictions and estimates and are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on Incyte'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 the efficacy or safety of the compounds in Incyte's pipeline, the results of further research and development, risks that results of clinical trials may be unsuccessful or insufficient to meet applicable regulatory standards, other market or economic factors, competitive and technological advances, and other risks detailed from time to time in Incyte's fillings with the Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the quarter ended March 31, 2014. Incyte disclaims any intent or obligation to update these forward-looking statements.

Source: Incyte Corporation

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