# Incyte Acquires Rights from Lilly to Develop and Commercialize Ruxolitinib (Jakafi®) for the Treatment of Patients with Graft-Versus-Host Disease (GVHD)

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- Pivotal development program for ruxolitinib in GVHD expected to begin in 2016
- Novartis agreement amended to include development and commercialization rights for ruxolitinib in GVHD outside of the U.S.

WILMINGTON, Del.--(BUSINESS WIRE)--Apr. 6, 2016-- Incyte Corporation (Nasdaq:INCY) today announced it has acquired the rights to develop and commercialize ruxolitinib (Jakafi®), its proprietary JAK1/JAK2 inhibitor, for graft-versus-host disease (GVHD) from Eli Lilly and Company (NYSE:LLY). Additionally, Incyte has amended its Collaboration and License Agreement with Novartis, granting Novartis exclusive research, development and commercialization rights for ruxolitinib in GVHD outside the U.S.

“We are committed to the research and development of innovative medicines that will benefit patients with serious diseases, like GVHD, where there are no approved treatments,” said Hervé Hoppenot, President and CEO, Incyte. “We are very pleased to be able to expand our development opportunities for ruxolitinib and plan to initiate a registration study in GVHD later this year as we seek to accelerate the availability of a treatment option for patients with this life-threatening disorder.”

Incyte and Lilly have agreed to amend their License, Development and Commercialization Agreement to enable Incyte to independently develop and commercialize ruxolitinib for GVHD. Incyte will make an upfront payment of $35 million to Lilly. The terms of the agreement also include additional potential payments by Incyte to Lilly upon the achievement of certain regulatory milestones.

Additionally, Incyte and Novartis have agreed to amend their Collaboration and License Agreement, granting Novartis the rights to research, develop and commercialize ruxolitinib for GVHD outside the U.S. Novartis will make payments to Incyte upon the achievement of certain development and regulatory milestones.

If approved, Incyte expects to commercialize ruxolitinib for GVHD in the U.S. and under the terms of the existing Collaboration and License Agreement would be eligible to receive potential milestone payments and royalties on sales of ruxolitinib in GVHD by Novartis outside the U.S.

**About GVHD**

Graft-versus-host disease (GVHD) is a condition that might occur after an allogeneic transplant (the transfer of genetically dissimilar stem cells or tissue). In GVHD, the donated bone marrow or peripheral blood stem cells view the recipient’s body as foreign and attack the body. There are two forms of GVHD; acute and chronic. GVHD is a significant cause of morbidity and mortality in transplant recipients. The skin, gastrointestinal (digestive) tract, and liver are the most commonly affected organs in patients with GVHD.

**About Ruxolitinib (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.

Ruxolitinib is not approved anywhere in the world as treatment for graft-versus-host disease.

Jakafi is marketed by Incyte in the United States and by Novartis as Jakavi® (ruxolitinib) outside the United States.

**Full Prescribing Information, including a more complete discussion of the risks associated with Jakafi, is available at 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, please visit www.incyte.com.

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**Forward Looking Statements**

Except for the historical information set forth herein, the matters set forth in this press release contain predictions, estimates and other forward-looking statements, including without limitation statements regarding: the Company’s plans and expectations for its GVHD development program, including the timing of the commencement of a registration study for ruxolitinib in GVHD, whether and when the Company will make additional payments to Lilly, and whether and when the Company will receive additional payments from Novartis. 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 the efficacy or safety of ruxolitinib, risks related to market competition, the results of and risks associated with further research and development, risks and uncertainties associated with sales, marketing and distribution requirements, risks that results of clinical trials may be unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development, the ability to enroll sufficient numbers of subjects in clinical trials, other market, economic or strategic factors and technological advances, unanticipated delays, the ability of the Company to compete against parties with greater financial or other resources, risks associated with the Company's dependence on its relationships with its

collaboration partners, greater than expected expenses, unanticipated or unpredictable expenses relating to litigation or strategic activities, our ability to obtain additional capital when needed, risks related to obtaining effective patent coverage for our products and other risks detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2015. The Company disclaims any intent or obligation to update these forward-looking statements.

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Source: Incyte Corporation

Incyte Corporation
**Media**
Catalina Loveman, +1 302 498 6171
cloveman@incyte.com
or
**Investors**
Michael Booth, DPhil, +1 302 498 5914
mbooth@incyte.com