FDA Accepts NDA Filing for Ruxolitinib as a Treatment for Myelofibrosis

August 3, 2011

- ***Application Granted Priority Review***
- ***PDUFA Date Set for December 3, 2011***

WILMINGTON, Del., Aug 03, 2011 (BUSINESS WIRE) --

Incyte Corporation (Nasdaq:INCY) announced today that the US Food and Drug Administration (FDA) has accepted for filing the New Drug Application (NDA) for Incyte's lead investigational compound, ruxolitinib (INCB18424/INC424), as a potential treatment for patients with myelofibrosis (MF). MF is a potentially life-threatening blood cancer with limited treatment options and no FDA-approved medicines. The FDA also has granted Incyte's request for Priority Review, which is given to investigational drugs that may offer either a major advance in treatment or provide a treatment where no adequate therapy exists. The FDA has a goal to complete the Priority Review within six months. Therefore, if the application is approved, Incyte anticipates that ruxolitinib could be available for US patients with MF in the fourth quarter of 2011.

The NDA includes results from two Phase III trials, COMFORT-I conducted by Incyte and COMFORT-II conducted by Novartis, under the Incyte-Novartis worldwide collaboration and license agreement. Results from both studies were recently presented at the 2011 American Society of Clinical Oncology annual meeting and the 16th Congress of the European Hematology Association.

About Myelofibrosis (MF)

Myelofibrosis is a potentially life-threatening blood cancer characterized by bone marrow failure, enlarged spleen (splenomegaly) and debilitating symptoms, such as fatigue, pruritus (severe itching), fever, night sweats, weight loss, bone pain and early satiety. MF is one of the Philadelphia chromosome-negative myeloproliferative neoplasms (MPNs), which also include polycythemia vera and essential thrombocythemia. Increased aberrant activation of the Janus kinase (JAK) pathway, which regulates blood cell production, has been associated with the development of the MPNs, including MF.[1]

About Ruxolitinib

Ruxolitinib, Incyte's lead JAK1 and JAK2 inhibitor, entered clinical testing in May 2007 and has shown clinical activity in a number of hematologic conditions. In addition to the recently completed Phase III studies in MF, ruxolitinib is currently being evaluated in a global Phase III registration study, RESPONSE, in patients with advanced polycythemia vera. This study is being conducted by Incyte in the US and Novartis outside of the US. Ruxolitinib is also being investigated in Phase II studies in patients with other hematologic malignancies and solid tumors.

About Incyte

Incyte Corporation is a Wilmington, Delaware-based drug discovery and development company focused on developing proprietary small molecule drugs for oncology and inflammation. For additional information on Incyte, visit the Company's web site at www.incyte.com.

Forward-Looking Statements

Except for the historical information contained herein, the matters set forth in this press release, including the statement regarding Incyte's anticipation that ruxolitinib could be available for US patients with MF in the fourth quarter of 2011 if the NDA is approved, are all 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 subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in the efficacy or safety of or unanticipated additional clinical trial results for ruxolitinib, the possibility that regulatory authorities may require additional clinical trials in order to support registration of ruxolitinib in any particular indication, the possibility that there may be other interpretations of the data produced in one or more of the clinical trials for ruxolitinib, the risk that regulatory authorities will require more extensive data for the ruxolitinib NDA filing or take longer to review the ruxolitinib NDA filing than currently expected, the results of further research and development, and other risks detailed from time to time in Incyte's filings with the Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the quarter ended June 30, 2011. Incyte disclaims any intent or obligation to update these forward-looking statements.

[1]Vannucchi AM, Guglielmelli P, Tefferi A. Advances in understanding and management of myeloproliferative neoplasms. *CA Cancer J Clin*. 2009;59:171-191.

SOURCE: Incyte Corporation

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