

Incyte's Ruxolitinib (INCB18424) Meets Primary Endpoint in Second Phase III Study

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- ***Data from Novartis COMFORT-II European Phase III trial show treatment with ruxolitinib provided a statistically significant reduction in spleen size in patients with myelofibrosis when compared with best available therapy***
- ***Myelofibrosis is a debilitating disease with a poor prognosis and limited therapies, presenting a critical unmet medical need***
- ***US New Drug Application submission by Incyte and EU Marketing Authorization Application submission by Novartis on track for Q2 2011***
- ***Complete data to be submitted by Novartis to an upcoming medical meeting***

WILMINGTON, Del., Mar 15, 2011 (BUSINESS WIRE) --

COMFORT-II, the second pivotal Phase III trial of Incyte Corporation's (Nasdaq: INCY) investigational Janus kinase (JAK) inhibitor, ruxolitinib (INCB18424 or INC424), has met its primary endpoint of significantly reducing spleen size in patients with myelofibrosis (MF), when compared to best available therapy. This trial was conducted by Novartis as part of the Incyte-Novartis worldwide collaboration and license agreement for ruxolitinib, an oral JAK1 and JAK2 inhibitor.

The European study, called COMFORT-II (COnTrolled MyeloEibrosis Study with ORal JAK Inhibitor Therapy), showed treatment with ruxolitinib provided a statistically significant reduction in spleen size in patients with primary MF, post-polycythemia vera myelofibrosis (PPV-MF), or post-essential thrombocythemia myelofibrosis (PET-MF), when compared with best available therapy, administered at doses and schedules determined by the investigator. The safety profile of ruxolitinib was consistent with previous studies. Complete study data will be submitted to an upcoming medical meeting.

"The positive results from the European COMFORT-II trial confirm the data from the US trials and further strengthen our confidence that ruxolitinib has the potential to provide myelofibrosis patients, and the physicians who treat them, a new approach to effectively manage this debilitating, life-threatening disease," stated Paul Friedman, M.D. President and CEO of Incyte. "We and Novartis will continue to work diligently to bring ruxolitinib forward as the first JAK1 and JAK2 inhibitor available to treat MF."

Data from the COMFORT-II and COMFORT-I clinical trials will form the basis of worldwide regulatory filings, planned to begin in the second quarter of 2011, first in the US followed by the EU. Both the European Commission (EC) and the United States Food and Drug Administration (FDA) have granted ruxolitinib orphan drug status for MF.

"The COMFORT-I and II trials constitute the largest clinical trial program to date in myelofibrosis. Data from these two Phase III trials demonstrate how treatment with ruxolitinib was more effective than placebo and any other available medical therapies," said Richard Levy, M.D., Executive Vice President and Chief Drug Development and Medical Officer of Incyte. "It is also very gratifying to see that the COMFORT-II safety profile is consistent with the previous studies."

About COMFORT-II

COMFORT-II is a randomized, open-label Phase III study of ruxolitinib (also known as INCB18424 or INC424) versus best available therapy that enrolled 219 patients with primary MF, PPV-MF or PET-MF in 56 study locations in Europe. Two-thirds received ruxolitinib and one-third received best available therapy, administered at doses and schedules determined by the investigator. The primary endpoint for COMFORT-II is the proportion of patients achieving a reduction in spleen volume of 35% or more from baseline to week 48 as measured by MRI (or CT scan in applicable patients). Reduction of spleen size is an accepted measurement for clinical improvement in MF^{1,2}. COMFORT-II is sponsored by Novartis⁵.

About Myelofibrosis (MF)

MF is an uncommon, life-threatening blood cancer characterized by bone marrow failure, enlarged spleen (splenomegaly), debilitating symptoms including fatigue, night sweats and pruritus, poor quality of life, and weight loss, as well as shortened survival². MF is one of the Philadelphia chromosome-negative myeloproliferative neoplasms (MPNs) which also includes polycythemia vera and essential thrombocythemia. Of the JAK-associated MPNs, MF carries the greatest risk of a poor prognosis, including transformation to fatal acute myelogenous leukemia, and there are currently no approved treatments for MF in the US^{2,3}. Although allogeneic stem cell transplantation may cure MF, the procedure is associated with significant morbidity and mortality and is usually appropriate only in younger patients⁴.

About Ruxolitinib (INCB18424)

Ruxolitinib is Incyte's lead internally developed JAK1 and JAK2 inhibitor that entered Phase I clinical testing in May 2007 and has shown clinical activity in a number of hematology and inflammatory conditions. The compound recently completed a Phase III program in myelofibrosis and is currently in a global Phase III registration trial, RESPONSE, in patients suffering from advanced polycythemia vera and a Phase II trial in patients with acute leukemias. Additional clinical studies evaluating ruxolitinib in other hematologic cancers and malignant diseases such as lymphoma and pancreatic cancer are planned for 2011.

Forward-Looking Statements

Except for the historical information contained herein, the matters set forth in this press release, including statements regarding a US New Drug Application submission by Incyte and the EU Marketing Authorization Application submission by Novartis for ruxolitinib being on track for second quarter 2011, that complete data will be submitted to an upcoming medical meeting, that the positive results from the European COMFORT-II trial confirm the data from the US trials and further strengthen our confidence that ruxolitinib has the potential to provide myelofibrosis patients, and the physicians who treat them, a new approach to effectively manage this debilitating, life-threatening disease, and that Incyte and Novartis will continue to work diligently to bring ruxolitinib forward as the first JAK1 and JAK2 inhibitor available to treat MF, 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 the high degree of risk and uncertainty associated with drug development and clinical trials, 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 than currently expected, future competitive or other market factors that may adversely affect the commercial potential for ruxolitinib, 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 Annual Report on Form 10-K for the year ended December 31, 2010. Incyte disclaims any intent or obligation to update these forward-looking statements.

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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.

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SOURCE: Incyte Corporation

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