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Incyte Reports Additional Analyses of Symptomatic Improvement and Quality of Life with Ruxolitinib (INC424) in Patients with Myelofibrosis from the COMFORT-I Study

June 11, 2011

Results Presented at 16th Congress of the European Hematology Association

LONDON, Jun 11, 2011 (BUSINESS WIRE) --

Incyte Corporation (Nasdaq:INCY) announced today additional symptom improvement and quality of life (QoL) results from COMFORT-I (**C**ontrolled **M**yelofibrosis Study with **O**ral JAK inhibitor **T**reatment), a randomized, double-blinded, placebo-controlled Phase III trial of Incyte's JAK1 and JAK2 inhibitor, ruxolitinib, in patients with myelofibrosis (MF). The data, being reported at the 16th EHA Congress today, demonstrated that treatment with ruxolitinib resulted in significant reductions in spleen volume and improvements in Total Symptom Score (TSS) while placebo-treated patients experienced progressive splenomegaly (enlarged spleen) and worsening of symptoms, complementing clinical results presented recently at the 2011 ASCO Annual Meeting.

The findings are being reported at the EHA Congress in Poster #0912: *Results Using the Modified Myelofibrosis Symptom Assessment Form (MFSAF v2.0) in COMFORT-I: a Randomized, Double-Blind, Phase III Trial of JAK1/2 Inhibitor Ruxolitinib vs. Placebo in Myelofibrosis*.¹ The presenting author is Ruben A. Mesa, M.D., Professor of Medicine, Chair, Division of Hematology & Medical Oncology, Mayo Clinic, Arizona. Dr. Mesa is a leading expert on the symptomatic burden of myelofibrosis and has been instrumental in developing tools, such as the modified MFSAF, for measuring these symptoms.

These data demonstrated that the primary endpoint of a 35% reduction in spleen volume was clearly associated with reduction of abdominal symptoms (abdominal discomfort, pain under the ribs and feeling of fullness (early satiety)) associated with an enlarged spleen. Importantly, many patients with less than 35% reduction in spleen volume also had meaningful improvement in abdominal symptoms. Patient benefit also was assessed using the Patient Global Impression of Change (PGIC), which measures patients' global assessment of change in their condition on a 7-point scale ranging from "very much worse" to "very much improved." While more than two-thirds of ruxolitinib-treated patients graded their disease as "much or very much improved" based on the PGIC, nearly three-quarters of placebo-treated patients reported "no change" or "worsening" on that scale.

In addition, of patients who had a 50% or greater reduction in TSS (a key secondary endpoint), nearly 90% rated their disease as "much or very much improved" based on the PGIC scale. Also, over 50% of patients with a 25% to 50% TSS improvement rated their disease as "much or very much improved," indicating that a significant proportion of these ruxolitinib-treated patients also had meaningful improvement in their disease. Associated with these improvements were improvements in almost all sub-scales of the European Organization for Research and Treatment of Cancer Quality-of-Life 30 Questionnaire (EORTC QLQ-C30), a standard and well-validated measure of quality of life in cancer patients. A copy of the poster presentation can be viewed by clicking on the following link: [EHA 2011 Ruben Mesa Poster](#).

Richard Levy, M.D., Incyte's Executive Vice President and Chief Drug Development and Medical Officer, stated, "Quality of life in patients with myelofibrosis can be severely compromised by massive splenomegaly and debilitating symptoms, and it is highly gratifying to see profound symptomatic improvement resulting in improved quality of life in MF patients."

As expected based on the mechanism of action of ruxolitinib, the most common adverse events occurring more frequently on ruxolitinib treatment than on placebo were anemia and thrombocytopenia. Both were manageable as evidenced by the low discontinuation rate as a result of these events (1 patient for each event in each arm of the study). Thrombocytopenia was managed with dose modifications and anemia was generally managed with transfusion. The prevalence of grade 3 and 4 anemia in ruxolitinib patients diminished over time as did the need for transfusion. Among the most frequently reported non-hematologic adverse events in ruxolitinib treated patients were dizziness, headache and bruising and were generally of low grade, and self limited with continued therapy.

About COMFORT-I

COMFORT-I is a randomized (1:1), double-blind, placebo-controlled Phase III study comparing the efficacy and safety of ruxolitinib to placebo in 309 patients with primary myelofibrosis (PMF), post-polycythemia vera myelofibrosis (PPV-MF) or post-essential thrombocythemia myelofibrosis (PET-MF) and involved over 80 clinical sites in the US, Canada and Australia.

The primary endpoint was the proportion of patients achieving a reduction in spleen volume of 35% or more from baseline to week 24 as measured by MRI (or CT scan in applicable patients). Key secondary endpoints included duration of maintenance of a 35% or greater reduction in spleen volume from baseline and the proportion of patients with 50% or more reduction in symptom improvement as measured by the MFSAF v2.0 electronic diary.

The study met its primary end-point and will be presented by Srdan Verstovsek, M.D., Ph.D., Associate Professor, Department of Leukemia, Division of Cancer Medicine, University of Texas - MD Anderson Cancer Center and Principal Investigator for COMFORT-I in the Presidential Symposium, one of the two plenary sessions at EHA, on June 11.

COMFORT-II, which was conducted by Novartis in the EU as part of the Incyte-Novartis worldwide collaboration and license agreement, is a randomized (2:1), open-label Phase III study of ruxolitinib versus best available therapy. COMFORT-II enrolled 219 patients with primary MF, PPV-MF or PET-MF in 56 study locations in Europe.

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), night sweats, bone pain and early satiety. MF is one of the Philadelphia chromosome-negative myeloproliferative neoplasms (MPNs), which also include polycythemia vera and essential thrombocythemia.² Aberrant activation of the Janus kinase

(JAK) pathway, which regulates blood cell production, has been associated with the development of the MPNs, including MF.³

Myelofibrosis is associated with poor prognosis and often results in a shortened survival. Up to 20% of patients can experience transformation to fatal secondary acute myelogenous leukemia within 10 years of diagnosis. Currently, there are limited treatment options and no FDA-approved medicines for MF; the only potential cure is allogeneic stem cell transplant, for which a very small proportion of patients qualify.²

About Ruxolitinib

Ruxolitinib is Incyte's lead internally developed JAK1 and JAK2 inhibitor that entered clinical trials in May 2007 and showed clinical activity in a number of hematologic disorders. This agent recently completed a global Phase III program (*COMFORT*) in myelofibrosis, and the New Drug Application is currently under review by the US Food & Drug Administration. Ruxolitinib also is in a global Phase 3 registration study, *RESPONSE*,⁴ in advanced polycythemia vera, a related hematologic neoplasm, as well as Phase 2 studies in patients with other hematologic malignancies and solid tumors. Other clinical studies evaluating ruxolitinib in patients with lymphoma and pancreatic cancer are planned.

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 statements regarding the presentation of the *COMFORT-I* results at one of the two plenary sessions at EHA on June 11 and other clinical studies evaluating ruxolitinib in patients with lymphoma and pancreatic cancer being planned, 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 studies, unanticipated developments in the efficacy or safety of ruxolitinib, the possibility that the outcomes for each of the planned clinical studies for ruxolitinib may not be favorable, the possibility that regulatory authorities may require additional clinical studies 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 Incyte's clinical studies, 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 March 31, 2011. Incyte disclaims any intent or obligation to update these forward-looking statements. Links to third-party websites or pages are provided for convenience only. Each website is subject to its own terms of use, and we encourage you to consult these policy statements. Incyte has no control over third party sites and does not endorse or recommend these sites, and expressly disclaims any responsibility for the accuracy of content or opinions set forth in any third-party website or your use of that information.

References

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