Positive Results Presented from Proof-of-Concept Phase II Clinical Trial of Incyte's Oral JAK1 Inhibitor in Patients with Myelofibrosis

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- ***In data presented at the 2013 ASH Annual Meeting, treatment with two out of three trial doses of INCB39110 provided meaningful improvements in myelofibrosis related symptoms***
- ***Data suggest JAK1 inhibition may result in less myelosuppression than use of JAK1/JAK2 inhibitors and JAK2 inhibitors***

NEW ORLEANS--(BUSINESS WIRE)--Dec. 9, 2013-- Incyte Corporation (Nasdaq: INCY) announced results of an interim analysis from a 12-week open-label, dose-escalation Phase II clinical trial involving more than 85 patients with intermediate or high-risk myelofibrosis (MF) for its proprietary oral JAK1 inhibitor, INCB39110. These results were presented today at the 2013 American Society of Hematology (ASH) Annual Meeting in New Orleans.

In this preliminary analysis of an ongoing Phase II trial that involved three doses (100 mg twice daily, 200 mg twice daily and 600 mg once daily), treatment with INCB39110 at doses of 200 mg twice daily and 600 mg once daily provided meaningful improvements in MF-related symptoms, including symptoms associated with splenomegaly. At week 12, 22.2 percent, 34.9 percent, and 50.0 percent of patients in the 100 mg twice daily, 200 mg twice daily, and 600 mg once daily dose groups, respectively, achieved at least a 50 percent improvement from baseline in their total symptom score (the primary endpoint); median percentage improvements from baseline at this time point were 28.5 percent, 45.8 percent, and 76.8 percent, respectively, across dose groups. Reductions in spleen volume were modest, with median percentage changes from baseline to week 12 of 5.0 percent, -14.1 percent, and -9.9 percent, respectively, across dose groups. The most common hematologic adverse events, regardless of causality, were anemia and thrombocytopenia, and the most common non-hematologic adverse events were fatigue, constipation and nausea. In comparison to JAK1/JAK2 inhibitors and JAK2 inhibitors, the findings from this analysis suggest that JAK1 inhibition may result in less myelosuppression. In patients not receiving post-baseline transfusions, mean hemoglobin levels in each dose group increased by week 2 and remained approximately 0.5 to 1.0 g/dL above baseline through week 12.

To access the presentation: ASH 2013 - Mascarenhas

“With the interim analysis of this trial combined with data from two other proof-of-concept trials in rheumatoid arthritis and psoriasis, we have a better understanding of JAK1 as a disease target, and we’re using this knowledge to focus the development of our broad portfolio of JAK1 inhibitors,” stated Richard S. Levy, M.D., Incyte’s Executive Vice President and Chief Drug Development and Medical Officer. “We are taking INCB39110, our most advanced JAK1 inhibitor, forward initially in solid tumors, starting with combinations that may not be as well-tolerated with a JAK1/JAK2 inhibitor as a result of the potential myelosuppressive effect of JAK2 inhibition.”

About the Study:

Mascarenhas J, et al. *An Open-Label, Phase II Study of the JAK1 Inhibitor INCB39110 in Patients with Myelofibrosis*

This Phase II proof-of-concept study involved men and women aged ≥18 years with primary myelofibrosis (MF), post-polycythemia vera MF, or post-essential thrombocythemia MF, irrespective of JAK2V617F mutation status, and classified as intermediate-1 or higher by Dynamic International Prognostic Scoring System (DIPSS). Patients were required to have a platelet count of ≥ 50 x 10^9/L, hemoglobin ≥ 8.0 g/dL (transfusions permitted to achieve these levels), and a palpable spleen or prior splenectomy.

The primary endpoint was the proportion of patients with a ≥ 50% reduction in total symptom score (TSS) from baseline as measured by the Myelofibrosis Symptom Assessment Form (MFSAF) v3.0 electronic diary at week 12 compared to baseline. Secondary endpoints included mean percentage change in TSS at week 12 compared to baseline; proportion of patients with ≥ 35 percentage reduction in spleen volume and mean percentage change in spleen volume at week 12 compared to baseline; and safety.

Three separate Simon-2 stage designs were used to assess separate dose cohorts (100 mg twice daily, 200 mg twice daily, and subsequently 600 mg once daily). A dose cohort could be expanded if at least three of the first 10 patients had at least a 50 percent improvement in TSS from baseline to week 12. The 200 mg twice daily and 600 mg once daily cohorts met the criteria for expansion, with a total of 45 and 32 patients enrolled, respectively, while the 100 mg twice daily cohort did not. Of the 32 patients enrolled in the 600 mg once daily dose group, nine had reached week 12 visit, and one had discontinued at the time of this interim analysis.

About Incyte

Incyte Corporation is a Wilmington, Delaware-based biopharmaceutical company focused on the discovery, development and commercialization of proprietary small molecule drugs for oncology and inflammation. For additional information on Incyte, please visit the Company's website at www.incyte.com.

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 and safety and therapeutic potential of INCB39110 and that JAK1 inhibition may result in less myelosuppression, 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 INCB39110, the results of further research and development, other market, economic or strategic factors and technological advances, 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 September 30, 2013. Incyte disclaims any intent or obligation to update these forward-looking statements.

Source: Incyte Corporation

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