

Data Presented At The American Society Of Hematology 49th Meeting Demonstrate That Incyte's Novel JAK Inhibitor, INCB18424, Provides Rapid and Profound Clinical Benefits in Myelofibrosis Patients

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WILMINGTON, Del.--(BUSINESS WIRE)--Dec. 10, 2007--Incyte (Nasdaq:INCY) announced today the presentation of interim Phase I/II results of INCB18424, its orally available janus-associated kinase (JAK) inhibitor in patients with myelofibrosis (MF). MF is a serious neoplastic condition with a survival rate of 3 to 7 years that is characterized by varying degrees of bone marrow failure, life-threatening splenic enlargement, and marked constitutional symptoms, resulting in a significant loss in quality of life.

Results presented at the American Society of Hematology 49th Meeting, involving 11 patients treated with INCB18424, demonstrate that:

- A profound and rapid reduction in splenomegaly, regardless of the presence of the JAK mutation, has been seen in all patients
- Mean reduction in spleen size reached 52% and 86% at months one and three, respectively, with similar responses at the two dose levels studied
- All six patients treated for three months or longer achieved clinical improvement as per the International Working Group (IWG) consensus criteria for treatment response in myelofibrosis
- All patients achieved significant improvements in quality of life
- INCB18424 was well tolerated at clinically effective doses with no off-target toxicities; no patients discontinued from study
- Of two transfusion-dependent patients treated for three to five months, one has become transfusion-independent

Thirty-two patients are currently enrolled in this ongoing Phase I/II study: eleven from the initial dose-escalation phase involving two doses of INCB18424 (25 mg BID and 50 mg BID), and an additional 21 patients in the expanded cohort arm, which is designed to further evaluate INCB18424 at the maximum tolerated dose (MTD), 25 mg BID.

Srdan Verstovsek, M.D., PhD., Associate Professor Leukemia Department, Myeloproliferative Disorders Program Leader, University of Texas M.D. Anderson Cancer Center, and the Principal Investigator for the study, stated, "All patients have demonstrated a marked, rapid and durable reduction in splenomegaly, which is a highly morbid and sometimes fatal component of myelofibrosis. Additionally, all patients have experienced significant improvements in their quality of life, including reduced fatigue, reduced malaise, increased appetite, weight gain or performance status."

Summary of Phase I/II Study in Patients with Primary Myelofibrosis (PMF) and Post-Polycythemia Vera (PV) and Post-Essential Thrombocythemia (ET)

Study Design:

A phase I/II trial of INCB18424 given orally twice-daily in patients with PMF and Post- PV/ET. Both JAK2 V617F and JAK2 wild type patients were eligible. PK and PD data were evaluated. Responses were evaluated using the IWG consensus criteria for treatment response in myelofibrosis.

Current Status:

Enrollment in the study has been completed. Eleven patients were enrolled in the Phase I dose-escalation portion and 21 patients were enrolled in the Phase II expanded cohort at the maximum tolerated dose of 25 mg BID. Duration of treatment ranges from three to five months in Phase I and from one to four weeks in Phase II. All patients are continuing on therapy.

Efficacy:

All patients have experienced a rapid substantial clinical benefit irrespective of the presence or absence of the JAK mutation and irrespective of whether the diagnosis was post-PV, post-ET or primary MF, suggesting that a broad spectrum of patients are likely to benefit from INCB18424. These clinical benefits include a striking reduction in splenomegaly, an improvement in patient symptoms including fatigue, malaise, pain, shortness of breath and wasting. Normalization of leukocytosis (2 of 4 patients) and thrombocytosis (2 of 3 patients) was observed following treatment with INCB18424.

Safety:

The 25 mg BID dose was established as the maximal tolerated dose (MTD) and was well tolerated in all patients. The dose limiting toxicity observed at 50 mg BID was thrombocytopenia, an expected toxicity of high level JAK inhibition. No off-target toxicities have been observed and no other laboratory or clinical toxicities were identified in this study.

Biomarker and Pharmacodynamic Results:

Significant reductions in the percentage of JAK2V617F: JAK2WT ratio was noted in peripheral blood and bone marrow. Aberrant JAK signaling, as measured by high levels of constitutively phosphorylated STAT3, commonly seen in the circulating leukocytes of MF patients was completely normalized within one month of treatment with INCB18424. Marked reduction in plasma levels of inflammatory cytokines and chemokines including IL-6, IL-8, TNF α , MIP-1, MCP-1, pro-thrombotic markers such as PAI-1, and angiogenic cytokines such as VEGF was observed within the first month of INCB18424 treatment. Rapid and significant elevation of hematopoietic growth factors such as erythropoietin, IL-3 and GM-CSF was observed following INCB18424 treatment. Together, these changes are believed to aid in the restoration of bone marrow function.

About Myeloproliferative Disease

Myeloproliferative diseases (MPDs) are a related group of hematological neoplasms characterized by dysfunction of the bone marrow resulting in either over production of blood cells or ineffective hematopoiesis leading to production of blood cells in the spleen and resulting in massive splenomegaly. The three main MPDs are polycythemia vera (PV), essential thrombocythemia (ET) and myelofibrosis (MF). Approximately 10 to 20% of patients with PV and ET progress to MF and MF can also develop without a prior history of PV or ET. The actual incidence of MPD is difficult to measure; research conducted in 2001 estimates that MPDs affect 4.7 people out of every 100,000. There is currently no known cure for these diseases and there are no adequately effective therapies.

About The Incyte JAK Inhibitor Program

There are four known JAK enzymes: JAK1, 2, 3 and TYK2. These enzymes are critical components of signaling mechanisms utilized by a number of cytokines and growth factors, including those that are elevated in MPD patients and which may contribute to poor quality of life in these patients. Pathways triggered by the JAKs are dysregulated in inflammation, myeloproliferative diseases, and other liquid and solid cancers.

INCB18424 is Incyte's lead internally developed JAK inhibitor. The compound is a potent JAK inhibitor that is greater than 100 fold selective against a broad panel of kinases and is being developed as an oral treatment for MF, rheumatoid arthritis and psoriasis. A Phase IIa study using the topical form of INCB18424 in mild-to-moderate psoriasis patients is also ongoing.

Incyte has discovered multiple potent, selective and orally bioavailable JAK inhibitors from multiple distinct chemical scaffolds. A lead follow-on compound is expected to enter clinical trials next year.

Webcast Information

Incyte is hosting a meeting to discuss the INCB18424 data as presented at the American Society of Hematology 49th Annual Meeting. The webcast is scheduled to begin at 7:15 p.m. ET on Monday, December 10, 2007 and can be accessed at: www.incyte.com under Investor Relations, Events and Webcasts.

The discussion will feature Srdan Verstovsek, M.D., Ph.D., Associate Professor, Leukemia Department, Myeloproliferative Disorders Program Leader, University of Texas M.D. Anderson Cancer Center, and Ayalew Tefferi, M.D., Professor of Hematology and Internal Medicine, Section Head for Myeloproliferative Disorders, Mayo Clinic.

An archive of this event will be available on the Incyte website until January 31, 2008.

About Incyte

Incyte Corporation is a Wilmington, Delaware-based drug discovery and development company focused on developing proprietary small molecule drugs to treat serious unmet medical needs. Incyte's pipeline includes multiple compounds in Phase I and Phase II development for HIV, diabetes, 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 with respect to expectations regarding the utility of INCB18424 as an oral treatment for myelofibrosis, rheumatoid arthritis and psoriasis, expectations regarding the initiation of clinical trials for a lead follow-on compound, expectations regarding the design of the ongoing Phase I/II oral myelofibrosis study and the effect of emerging data on those designs 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 associated with drug development and clinical trials, results of further research and development, the impact of competition and of technological advances and the ability of Incyte to compete against parties with greater financial or other resources, Incyte's ability to enroll a sufficient number of patients for its clinical trials, 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, 2007. Incyte disclaims any intent or obligation to update these forward-looking statements.

CONTACT:

Incyte
Pamela M. Murphy
Vice President, Investor Relations/
Corporate Communications
302-498-6944

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