

Incyte's Selective JAK1 / 2 Inhibitor, INCB18424, Demonstrates Rapid and Durable Clinical Benefits in Myelofibrosis Patients

December 6, 2008

Incyte to Present Additional Data at 50th American Society of Hematology Annual Meeting in San Francisco

WILMINGTON, Del.--(BUSINESS WIRE)--Dec. 6, 2008--Incyte Corporation (Nasdaq: INCY) will present updated results from an ongoing Phase II trial of INCB18424, its selective, orally available Janus kinase (JAK) inhibitor, in patients with myelofibrosis (MF) at the 50th American Society of Hematology (ASH) Annual Meeting.

MF is a serious neoplastic condition characterized by varying degrees of bone marrow failure, splenic enlargement and debilitating constitutional symptoms resulting in a significant loss in quality of life and reduced life-span. There are currently no approved treatments for patients with myelofibrosis.

Srdan Verstovsek, M.D., Ph.D., Associate Professor, Leukemia Department, Myeloproliferative Disorders Program Leader, University of Texas M.D. Anderson Cancer Center, and the principal investigator for the Phase II trial, stated, "Over the past 18 months, nearly 150 MF patients have been enrolled in the Phase II trial, INCB18424-251. Important and previously unachievable clinical benefits observed in this study include striking improvement in splenomegaly and the debilitating constitutional symptoms that plague the majority of these patients. INCB18424 treatment improves the systemic inflammatory state which we know characterizes advanced MF. INCB18424 results in prompt and sustained reductions in the markedly elevated levels of a broad range of pro-inflammatory cytokines that we have now documented in MF patients. Additionally, regardless of an MF patient's diagnostic subgroup or the presence or absence of JAK2 mutations which occur in subsets of MF patients, the vast majority of patients entering this trial remain on study, many for a year or more, with durable and robust clinical benefit."

Richard Levy, M.D., Incyte's Senior Vice President, Drug Development, added, "The updated data set, much of which will be summarized at ASH, confirms that long term INCB18424 treatment has been well tolerated and results in durable clinical improvement in splenomegaly, constitutional symptoms, and cachexia. New data also demonstrate improvement in exercise tolerance and confirmation of spleen size reduction as measured by MRI. Importantly, this clinical experience gives us the confidence to select registration endpoints and the dosing regimen for the Phase III program which we expect will support US and international registrations. We plan to start Phase III in the first half of 2009 following FDA approval of a special protocol assessment."

The most current data from the ongoing Phase II trial will be described in four posters to be presented at the ASH meeting (to access copies of these posters, please go to: http://library.corporate-ir.net/library/69/697/69764/items/317459/INCY_ASH2008.pdf)

1760: INCB018424, a Selective JAK1/2 Inhibitor, Significantly Improves the Compromised Nutritional Status and Frank Cachexia in Patients with Myelofibrosis (MF)

Ruben A. Mesa, MD, FACP, Srdan Verstovsek, Hagop M. Kantarjian, MD, Animesh D. Pardanani, MBBS, PhD, Steven Friedman, MD, Robert Newton, Susan Erickson-Viitanen, Deborah Hunter, John Redman, MD, Swamy Yeleswaram, Edward Bradley, MD and Ayalew Tefferi, MD

1762: The JAK Inhibitor, INCB018424, Demonstrates Durable and Marked Clinical Responses in Primary Myelofibrosis (PMF) and Post-Polycythemia Vera/Essential Thrombocythemia Myelofibrosis (Post PV/ET-MF)

Srdan Verstovsek, Hagop M. Kantarjian, MD, Animesh D. Pardanani, MBBS, PhD, Deborah Thomas, MD, Jorge Cortes, MD, Ruben A. Mesa, MD, FACP, William J. Hogan, MBChB, John R. Redman, MD, Sue Erickson-Viitanen, Richard Levy, MD, Kris Vaddi, PhD, DVM, Edward Bradley, MD, Jordan Fridman, PhD and Ayalew Tefferi, MD

2804: The Clinical Phenotype of Myelofibrosis Encompasses a Chronic Inflammatory State that is Favorably Altered by INCB018424, a Selective Inhibitor of JAK1/2

Ayalew Tefferi, MD, Hagop M. Kantarjian, Animesh D. Pardanani, MBBS, PhD, Ruben A. Mesa, MD, FACP, Robert C. Newton, PhD, Peggy A. Scherle, PhD, Timothy Burn, PhD and Srdan Verstovsek

2802: Characterization of JAK2 V617F Allele Burden in Advanced Myelofibrosis (MF) Patients: No Change in V617F:WT JAK2 Ratio in Patients with High Allele Burdens despite Profound Clinical Improvement Following Treatment with the JAK Inhibitor, INCB018424

Srdan Verstovsek, MD, PhD, Hagop M. Kantarjian, MD, Animesh D. Pardanani, MBBS, PhD, Timothy Burn, PhD, Kris Vaddi, PhD, DVM, John Redman, MD, Edward C. Bradley, MD, Richard Levy, MD, Steven Friedman, MD, Gregory Hollis, PhD and Ayalew Tefferi, MD

Phase II Study Design

Study INCB18424-251 is an ongoing Phase II trial in patients with primary myelofibrosis (PMF), post-polycythemia vera myelofibrosis (post-PV/MF), and post-essential thrombocythemia myelofibrosis (post-ET/MF) with both mutated JAK2 (V617F mutation) and normal JAK2 (wild type). To date, 148 patients have been enrolled in the Phase II trial, which includes several different twice-daily and once-daily doses. Primary objectives of the study include:

- The determination of the safety and efficacy of INCB18424 treatment in MF patients
- Evaluation of twice-daily and once-daily dosing regimens to identify an optimal dosing paradigm for use in future clinical trials

-- Prospective identification of functional measures of clinical efficacy

In this ongoing Phase II trial, INCB18424 has been well tolerated, with no off-target toxicities. Reversible thrombocytopenia is the dose-limiting toxicity and has been effectively managed by dose reduction and/or interruption of therapy. The median duration of treatment with INCB18424 is approximately 7 months.

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. 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, PV and ET, multiple myeloma, hormone refractory prostate cancer, and rheumatoid arthritis and as a topical treatment for psoriasis.

Incyte has discovered multiple potent, selective and orally bioavailable JAK inhibitors from multiple distinct chemical scaffolds. A lead follow-on compound, INCB28050, is in Phase Ib development.

Webcast Information

Incyte is hosting a meeting to discuss the INCB18424 data presented at the 50th American Society of Hematology Annual Meeting. The webcast is scheduled to begin at 7:30 p.m. PT (10:30 p.m. ET) on Monday, December 8, 2008, 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 Richard Levy, M.D., Senior Vice President, Drug Development, Incyte.

A replay of this event will be available and can be assessed at: www.incyte.com.

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 oncology, inflammation and diabetes.

Forward Looking Statements

Except for the historical information contained herein, the matters set forth in this press release, including statements with respect to clinical experience giving the confidence to select registration endpoints and the dosing regimen for a Phase III program which we expect will support US and international registrations, plans to start Phase III in the first half of 2009 following FDA approval of a special protocol assessment for INCB18424 for myelofibrosis, plans to describe the most current data from the ongoing Phase II clinical trial of INCB 18424 in myelofibrosis at ASH, plans to develop INCB18424 as an oral treatment for MF, PV and ET, multiple myeloma, hormone refractory prostate cancer, and rheumatoid arthritis and as a topical treatment for psoriasis, 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, the uncertainty of the FDA approval process, 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, 2008. Incyte disclaims any intent or obligation to update these forward-looking statements.

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