



**FOR IMMEDIATE RELEASE**

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**Incyte's Novel JAK Inhibitor Demonstrates Rapid Clinical Benefits in  
Ongoing Phase I/II Myelofibrosis Study**

*Results Presented Today at the 2008 American Society of  
Clinical Oncology Annual Meeting*

**Wilmington, DE – June 2, 2008** - Incyte Corporation (Nasdaq: INCY) announced today the presentation of clinical results from a Phase I/II study of INCB18424, its orally available janus-associated kinase (JAK) inhibitor, in patients with myelofibrosis. Myelofibrosis (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 study, presented the findings today in an oral presentation at the 2008 American Society of Clinical Oncology Annual Meeting (abstract # 7004).

Dr. Verstovsek stated, "This study continues to demonstrate that JAK1/2 inhibition can lead to rapid clinical benefits in myelofibrosis patients, including unprecedented reductions in splenomegaly which affects the majority of these patients. We have also seen impressive and clinically meaningful reductions in fatigue, night sweats and pruritus, as well as increased appetite and weight gain in the majority of treated patients – all of which are important improvements in their clinical condition.

"In addition to these benefits, INCB18424 has been well tolerated. Reversible thrombocytopenia is the dose limiting toxicity and has been effectively managed by dose reduction and/or interruption of therapy. Based on the results across multiple dose levels, I am confident that optimal dosing regimens with

INCB18424 can be defined to provide safe and effective treatment of this underserved and highly heterogeneous patient population.”

## Summary of ASCO Results

### *Study Design:*

This is an ongoing phase I/II trial in patients with primary myelofibrosis and post-polycythemia (PV) and post-essential thrombocythemia (ET) myelofibrosis. Patients with both mutated JAK2 (V617F mutation) and normal JAK2 (wild type) are eligible. Primary objectives of the study include:

- determine safety and efficacy of INCB18424 treatment in MF patients
- evaluate twice-daily and once-daily dosing regimens to identify an optimal dosing paradigm for use in future clinical trials
- prospectively identify functional measures of clinical efficacy

### *Efficacy:*

The presentation today involved 27 patients receiving 25 mg twice-daily and 12 patients receiving 10 mg twice-daily. Preliminary results from once-daily regimens were also presented. These results demonstrate that treatment with INCB18424 provided:

- rapid and profound reductions in splenomegaly / hepatomegaly. Mean organ size reduction of  $\geq 50\%$  was achieved in 71% and 42% of patients treated with 25 mg twice-daily and 10 mg twice-daily, respectively. The majority of these reductions occurred within one month of treatment
- greater than 50% reduction in constitutional symptoms including fatigue, pruritus and night sweats in patients presenting with these symptoms
- striking reduction in proinflammatory cytokines was also noted, including reduction in IL-6, IL-1, IL-18, IL-1ra and TNF, and also reduction in chemokines, including MCP-1, MIP-1 and IL-8. Many of these cytokines are believed to mediate the debilitating constitutional symptoms in myelofibrosis
- improvement in body weight, possibly resulting from an improved appetite and reduced inflammatory cytokines
- improvement in the Eastern Cooperative Oncology Group (ECOG) performance status with the majority of patients achieving a score of 0
- reduction in growth factors involved in bone marrow pathology, including VEGF, basic FGF and EGF, and increased erythropoietin were also observed in a number of patients.

### *Safety:*

INCB18424 was very well tolerated with no off-target toxicities. Adverse events at 25 mg BID were mild to moderate in severity and included (related and unrelated): diarrhea (2), edema (2), dyspnea (2), rash (2) and urinary tract infection (2). The only adverse event in the 10 mg BID cohort was a urinary tract infection (1).

Adverse hematological effects of INCB18424 included grade 3 and 4 thrombocytopenia and anemia and were seen in 8 and 2 patients respectively, with one patient experiencing both. These events were reversible and manageable through dose reduction and/or drug interruption in the majority of patients.

### **Current Status of Ongoing Phase I/II Trial**

Ninety three patients have been enrolled in this ongoing Phase I/II study, which includes several different twice-daily and once-daily doses. Approximately 50 additional patients are expected to enroll in this study over the next several months to provide the basis for finalizing the optimal dose regimen and to prospectively evaluate functional measures of clinical efficacy.

### **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 >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 an oral and 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 is scheduled to begin Phase I trials this month.

### **Webcast Information**

Incyte is hosting a meeting to discuss the INCB18424 data presented at the 2008 American Society of Clinical Oncology Annual Meeting. The webcast is scheduled to begin at 8:45 p.m. ET on Monday, June 2, 2008, and can be accessed at: [www.incyte.com](http://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.

An archive of this event will be available on the Incyte website.

### **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. For additional information on Incyte, visit the Company's web site at [www.incyte.com](http://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 the potential value of the JAK inhibitor program, ability to refine optimal dosing regimens with INCB18424, our plans to finalize the dosing regimen and prospectively evaluate functional measures of clinical efficacy, and plans to begin Phase I trials for a lead follow-on JAK inhibitor compound, 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 March 31, 2008. Incyte disclaims any intent or obligation to update these forward-looking statements.