

# Data from Three Phase II Trials to be Presented at the 51st American Society of Hematology Annual Meeting Demonstrate that INCB18424, a Selective JAK1/JAK2 Inhibitor, Has Potential in Multiple Hematology Conditions

December 7, 2009

• Continues to Demonstrate Rapid and Durable Clinical Benefits in Myelofibrosis Patients

# • Provides Clinically Meaningful Improvements in Patients with Advanced Polycythemia Vera and Essential Thrombocythemia

# • Demonstrates Clinical Benefit in Patients with Secondary Acute Myeloid Leukemia

WILMINGTON, Del.--(BUSINESS WIRE)--Dec. 7, 2009-- Incyte Corporation (NASDAQ: INCY) announced this morning that INCB18424 (also referred to as INCB018424), its selective, orally available janus kinase (JAK) inhibitor, will be the subject of three oral presentations at the 51<sup>st</sup> American Society of Hematology (ASH) Annual Meeting in New Orleans.

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 INCB18424 myeloproliferative neoplasms clinical programs, stated, "INCB18424 continues to provide durable and previously unachievable clinical benefits in patients with myelofibrosis with or without JAK2 activating mutations. It is equally gratifying to see significant clinical benefits in patients with advanced polycythemia vera and essential thrombocythemia including normalization of blood counts, normalization of hematocrit without the need for phlebotomy, rapid and durable reductions in enlarged spleens as well as rapid and durable reductions in symptoms, particularly pruritus.

"Additionally, in an exploratory trial in highly refractory patients with secondary acute myeloid leukemia and other leukemias for which no standard therapies are likely to lead to a durable remission, it is encouraging to see patients obtain clinical benefit including the achievement of stable disease as well as complete and partial responses. Our experience with INCB18424 in these highly refractory leukemia patients, along with the growing body of evidence indicating that JAK activation may play a determining role in a number of hematologic malignancies, suggests that use of a selective JAK inhibitor may help provide underserved patients in multiple hematological cancers with improved clinical outcomes."

Richard Levy, M.D., Incyte's Executive Vice President, Chief Drug Development and Medical Officer, added, "The updated data from the Phase II trial in myelofibrosis, our most advanced program for INCB18424, demonstrate that the dosing regimens that are being used in our Phase III trials, COMFORT-I and COMFORT-II, have the potential to be well tolerated and provide durable clinical improvement in both splenomegaly and the debilitating constitutional symptoms seen in the majority of MF patients.

"COMFORT-I and II are currently enrolling patients diagnosed with myelofibrosis, either primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis, regardless of the presence or absence of the JAK V617F mutation. Additionally, in both studies, patients not randomized to receive INCB18424 will have the opportunity to cross over to receive this investigational therapy."

For information on the INCB18424 Phase III trials go to:

- INCB18424: COMFORT-I Phase III Trial in the US, Canada and Australia<a href="http://www.clinicaltrials.gov/ct2/show/NCT00952289?term=incyte&rank=4">http://www.clinicaltrials.gov/ct2/show/NCT00952289?term=incyte&rank=4</a>
- INCB18424: COMFORT-II Phase III Trial in Europe<u>http://www.clinicaltrials.gov/ct2/show/NCT00934544?term=INCB018424&</u> rank=10

For patient referral information on COMFORT-I and COMFORT-II please go to: <u>http://www.comfortstudy.com</u> or call 1-877-9-MFSTUDY.

# **INCB18424 Oral Presentations at ASH**

Below are the titles, sessions, times and names of the presenters for the three oral presentations involving INCB18424. Copies of the presentations will be available immediately after each oral presentation at: <u>http://www.incyte.com/</u> Incyte will also host a webcast of a meeting to discuss these results (for details see below).

• A Phase II Study of INCB018424, An Oral, Selective JAK1/JAK2 Inhibitor, in Patients with Advanced Polycythemia Vera (PV) and Essential Thrombocythemia (ET) Refractory to Hydroxyurea (Abstract #311)

Session Name:	Myeloproliferative Syndromes: Clinical
Presentation Time:	8:00 a.m. Monday, December 7, 2009
Name of Presenter:	Srdan Verstovsek, M.D., Ph.D. MD Anderson

• Significant Activity of the JAK2 Inhibitor, INCB018424 in Patients with Secondary, Post-Myeloproliferative Disorder Acute

Myeloid Leukemia: Results of An Exploratory Phase II Study (Abstract #631)

Session Name: Acute Myeloid Leukemia - Therapy, excluding Transplantation II Presentation Time: 4:30 p.m. Monday, December 7, 2009 Name of Presenter: Farhad Ravandi, M.D. - MD Anderson

• Long-Term Follow up and Optimized Dosing Regimen of INCB018424 in Patients with Myelofibrosis: Durable Clinical, Functional and Symptomatic Responses with Improved Hematological Safety (Abstract #756)

Session Name:	Myeloproliferative Syndromes: Myeloproliferative Neoplasms - Clinical Features and Therapeutics
Presentation Time:	5:45 p.m. Monday, December 7, 2009
Name of Presenter:	Srdan Verstovsek, M.D., Ph.D MD Anderson

## **ASH Webcast Information**

Incyte is hosting a meeting to discuss the INCB18424 data presented at the 51<sup>st</sup>American Society of Hematology Annual Meeting. The webcast is scheduled to begin at 9:30 p.m. ET (8:30 p.m. CT/6:30 p.m. PT) on Monday, December 7, 2009, and can be accessed at: <u>http://www.incyte.com/</u> 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., Executive Vice President, Chief Drug Development and Medical Officer, Incyte. A replay of this event will also be available and can be assessed at: <a href="http://www.incyte.com/">http://www.incyte.com/</a>

# About INCB18424

INCB18424 is Incyte's lead internally developed JAK1/JAK2 inhibitor that has shown positive clinical activity in a number of hematology and inflammatory conditions. The compound is currently in Phase III for patients with MF and Phase II for patients with advanced PV and ET. Incyte recently announced a major collaboration and license agreement with Novartis in which Incyte will retain exclusive rights for the development and potential commercialization of INCB18424 in the US. Novartis will have responsibility for the future development and commercialization of INCB18424 in all hematology–oncology indications outside of the US. In clinical trials INCB18424 has been generally well tolerated. The most commonly reported adverse events include reversible thrombocytopenia and anemia, self-limited diarrhea, fatigue and headache.

# About Myeloproliferative Neoplasms (MPNs)

MPNs 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 MPNs 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 are no adequately effective therapies to treat these disorders.

# About Secondary Acute Myeloid Leukemia (AML)

Acute myeloid leukemia (AML), also known as acute myelogenous leukemia, is characterized by the rapid growth of abnormal white blood cells of the myeloid lineage called blasts that accumulate in the bone marrow and blood, and interfere with the production of normal blood cells. Adult AML is uniformly fatal if not treated but is potentially curable with standard chemotherapy, with or without stem cell transplantation.

While the cause of AML remains unknown, when AML arises in patients previously diagnosed with a myeloproliferative neoplasm, myelodysplastic syndrome or other hematologic disorders, it is known as secondary AML. Secondary AML is more likely to be associated with resistance to standard chemotherapy and has a poor overall prognosis. Secondary AML is also most often seen in elderly patients and estimated to account for approximately 25 - 40% of cases in this group.

### About Incyte

Incyte Corporation is a Wilmington, Delaware-based drug discovery and development company focused on developing proprietary small molecule drugs for oncology, inflammation and diabetes. Incyte's most advanced compound, INCB18424, is in Phase III development for myelofibrosis. For additional information on Incyte, visit the Company's web site at <a href="http://www.incyte.com/">http://www.incyte.com/</a>

## **Forward Looking Statements**

Except for the historical information contained herein, the matters set forth in this press release, including statements with respect to the ongoing clinical experience with INCB18424 and the dosing regimen for the Phase III program which has the potential to be well tolerated and provide durable clinical improvement in splenomegaly and constitutional symptoms, plans to describe the most current data from the ongoing Phase II clinical trials of INCB18424 in myelofibrosis, PV and ET and AML at ASH, 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, 2009. Incyte disclaims any intent or obligation to update these forward-looking statements.

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