Incyte Presents Positive Long-Term Results from Ongoing Phase II Trial of INCB18424 in Advanced Polycythemia Vera (PV) and Essential Thrombocythemia (ET) at the American Society of Hematology Annual Meeting

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- **Data provide further evidence of potential broad clinical utility of INCB18424, the most advanced, selective JAK1 and JAK 2 inhibitor in development to treat myeloproliferative neoplasms (MPNs)**
- **Top-line data from U.S. Phase III clinical study (COMFORT-I) in myelofibrosis (MF) expected this month**
- **Global Phase III clinical trial (RESPONSE) in PV enrolling in the U.S.**

WILMINGTON, Del., Dec 06, 2010 (BUSINESS WIRE) --

Incyte Corporation (NASDAQ:INCY)presentedpositive long-term clinical results today from an ongoing open-label Phase II trial for INCB18424, its selective, oral JAK1 and JAK2 inhibitor, in patients with advanced polycythemia vera (PV) and essential thrombocythemia (ET). PV and ET, along with myelofibrosis (MF), are blood cancers that belong to a group of diseases known as myeloproliferative neoplasms (MPNs). The data showing long-term clinical activity, including reduction in spleen size, phlebotomy independence (in PV patients) and improvement in blood counts lasting up to 27 months, were presented in an oral session (Abstract #313) at the 52nd American Society Hematology Annual Meeting in Orlando, FL. (ASH PV/ET Presentation)

"These positive and sustained results in PV and ET achieved across multiple endpoints, combined with the positive data we've reported in MF, further support our confidence in the potential broad utility of INCB18424," said Paul A. Friedman, M.D., Incyte President and Chief Executive Officer. "With our forthcoming Phase III MF results and the recent initiation of the Phase III trial in PV with our partner Novartis, INCB18424 is the most advanced JAK inhibitor compound in development for MPNs."

With a median duration of 21 months of follow-up, clinical responses observed in 34 patients enrolled with PV included durable improvements in splenomegaly (spleen enlargement), hematocrit control and symptomatic burden including pruritus, night sweats and bone pain. Clinical responses seen in 39 patients enrolled with ET included long-term reductions in elevated platelet and white blood cell counts, and, when present, splenomegaly and constitutional symptoms.

"It is encouraging to see that treatment with INCB18424 provided long-term clinical benefit in this Phase II trial, with ongoing responses observed in patients who now have up to 27 months of follow-up," said Srdan Verstovsek, M.D., Ph.D., Associate Professor, Leukemia Department, Myeloproliferative Disorders Program Leader, University of Texas M.D. Anderson Cancer Center, and INCB18424 principal investigator. "This is particularly notable given the fact that the enrolled patient populations were refractory to, or intolerant of, hydroxyurea, our current standard of care for these chronic and under-served disorders. Importantly, INCB18424 has been well tolerated in these advanced patients, with mechanism-based hematologic changes effectively managed with individualized dose titration."

Study 18424-256 is an ongoing, multi-center, single-arm, open-label Phase II study being conducted in the United States and Italy. An initial 8-week run-in evaluation established 10 mg and 25 mg twice daily as starting doses for expansion cohorts in PV and ET, respectively; dose adjustments for safety and efficacy were allowed so that each patient could be titrated to his or her most appropriate dose.

Key Efficacy Findings

PV patients: After a median follow-up of 21 months, 97% of enrolled patients (n=34) achieved hematocrit control to less-than or equal to 45% in the absence of phlebotomy. All patients continued to maintain phlebotomy-independence at the time of their last follow-up visit. Splenomegaly was present in 74% of patients at entry; 80% of patients achieved a greater-than or equal to 50% reduction in palpable spleen length and 68% have achieved complete resolution. Leukocytosis (white blood cell count elevation > $15x10^9$/L) was present in 44% of patients at baseline, and counts normalized in 73%. Thrombocytosis (platelet count elevation > $600x10^9$/L) was present in 38% of subjects at baseline, and counts normalized in 69%. Improvements in patient reported symptoms of pruritus, bone pain, and night sweats have been observed in the majority of patients as of the last follow-up visit.

ET patients: After a median follow-up of 21 months, 49% of enrolled patients (n=39) normalized platelet counts, and 79% achieved platelet counts < $600x10^9$/L or a greater-than or equal to 50% reduction from baseline. Of the 14 patients with extreme thrombocytosis > $1000x10^9$/L at baseline, 13 (93%) experienced > 50% reduction. WBC counts for patients with baseline counts > $10x10^9$/L normalized within the first month and were maintained for a median duration of 14 months. Palpablespleens completely resolved in 3 of 4 patients with baseline splenomegaly; 1 reduced >50% from baseline.

Safety

The adverse events associated with INCB18424 in this study were consistent with the safety profile established by previous trials with INCB18424 in MPNs. Drug-related adverse events were generally mild-to-moderate in intensity and manageable with dose adjustments.

PV patients: Six patients (18%) discontinued therapy (2 for adverse events (AEs), 2 withdrew consent, 1 for no response and 1 for disease progression). Grade 3 AEs potentially related to study medication included thrombocytopenia (2), neutropenia (1), renal tumor (1), asthenia (1), viral

infection (1), and atrial flutter (1). No Grade 4 drug-related AEs have occurred.

ET patients: Eleven patients (28%) discontinued therapy (4 for AEs, 2 withdrew consent, 5 for no response). Grade 3 AEs potentially related to study medication included leukopenia (2 patients), GI disorder (1), and peripheral neuropathy (1). No Grade 4 drug-related AEs have occurred.

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. The three main Philadelphia-negative MPNs are myelofibrosis, polycythemia vera and essential thrombocythemia.

Myelofibrosis is associated with bone marrow failure, splenomegaly and debilitating symptoms, transformation to acute myelogenous leukemia and shortened survival. MF occurs as primary or secondary MF. Primary MF presents as MF without any other etiology. Secondary MF includes post-polycythemia vera MF and post-essential thrombocythemia MF, which are progressions of PV or ET to MF.

Polycythemia vera is a blood cancer characterized by the overproduction of red blood cells which increases blood viscosity and leads to elevated thromboembolic risk. Increased levels of white blood cells and platelets are also common. In advanced disease, patients frequently exhibit spleen enlargement and debilitating symptoms including pruritus, night sweats, fatigue, and muscle and bone pain.

Essential thrombocythemia is characterized by uncontrolled proliferation of myeloid lineage cells, especially megakaryocytes, leading to the overproduction of platelets. Common complications include thrombotic events and bleeding. Patients with advanced essential thrombocythemia may also experience splenomegaly as well as symptoms including fatigue, headache, night sweats, and muscle and bone pain.

About INCB18424

INCB18424 is Incyte's lead internally developed JAK1 and JAK2 inhibitor that entered Phase I clinical testing in May 2007 and has shown positive clinical activity in a number of hematology and inflammatory conditions.

In November 2009, Incyte and Novartis announced a collaboration and license agreement for two hematology-oncology programs in which Incyte retained exclusive rights to develop and commercialize INCB18424 in the U.S. and Novartis received exclusive rights to develop and commercialize INCB18424 for territories outside the U.S. Novartis also received worldwide rights for Incyte's cMET Inhibitor, INCB28060.

The compound is currently in Phase III development for patients with myelofibrosis and for patients with advanced polycythemia vera. A global Phase III registration trial called RESPONSE (**R**andomized, open label, multicenter phase III study of **E**fficacy and **S**afety in **PO**lycythemia vera subjects who are resistant to or intolerant of hydroxyurea: JAK i**N**hibitor INC424 tablets ver**S**us b**E**st available care) is now open to enrollment in the U.S. (for additional information go to: ClinicalTrials.gov identifier: NCTO1243944 or http://www.responsetrial.com) and will open in countries outside the U.S. in early 2011.

About Incyte

Incyte Corporation is a Wilmington, Delaware-based drug discovery and development company focused on developing proprietary small molecule drugs for 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 that the data from an ongoing Phase II trial of INCB18424 in PV provide further evidence of potential broad clinical utility of INCB18424 and show potential long-term clinical activity, including reduction in spleen size, phlebotomy independence (in PV patients) and improvement in blood counts lasting up to 27 months, that top-line data from a U.S. Phase III clinical study (COMFORT-I) in myelofibrosis are expected this month, 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 and uncertainty associated with drug development and clinical trials, the ability to enroll a sufficient number of patients, unanticipated developments in the efficacy or safety of INCB18424, the results of further research and development, 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, 2010. Incyte disclaims any intent or obligation to update these forward-looking statements.

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