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Incyte Reaches Agreement with FDA on a Special Protocol Assessment for INCB18424 in Myelofibrosis

COMFORT– I, a Pivotal Phase III Clinical Trial, to Begin in the United States, Canada and Australia

Wilmington, DE – July 21, 2009 -- Incyte Corporation (Nasdaq: INCY) announced today that it has reached agreement with the U.S. Food and Drug Administration (FDA) regarding a Special Protocol Assessment (SPA) on the design of a pivotal Phase III trial for its lead JAK1/JAK2 Inhibitor, INCB18424, in patients with primary myelofibrosis (PMF), post-polycythemia vera myelofibrosis (PPV-MF) or post-essential thrombocytemia myelofibrosis (PET-MF). The SPA provides agreement that the study design and planned analysis of the Phase III trial adequately address objectives in support of a regulatory submission.

COMFORT-I (COntrolled MyeloFibrosis Study with ORal JAK Inhibitor Treatment), is a double-blind, placebo-controlled Phase III trial comparing the efficacy and safety of INCB18424 to placebo in approximately 240 patients with PMF, PPV-MF or PET-MF. COMFORT-I is expected to begin in August. COMFORT-II, a second Phase III trial being conducted in Europe, began patient enrollment in July.

Paul A. Friedman, M.D., Incyte's President and CEO, stated, “Finalization of the SPA is an important achievement and we look forward to initiating COMFORT-I as quickly as possible in over 90 clinical sites in the U.S., Canada and Australia. The primary endpoint of COMFORT-I is the proportion of patients achieving a 35% or greater reduction in spleen volume as compared to patients receiving placebo. Key secondary endpoints include measuring the duration of the 35% or greater reduction in spleen volume among the patients initially randomized to INCB18424, and the proportion of patients who achieve a 50% or greater reduction in symptoms as measured by a modified version of the Myelofibrosis Symptom Assessment Form.”

Richard Levy, M.D., Incyte’s Executive Vice President, Chief Drug Development and Medical Officer, stated, “Based on our current estimates for patient recruitment of COMFORT-I, and assuming that results from the trial are positive, we anticipate filing the New Drug Application for INCB18424’s use in MF in late 2010 or early 2011.”
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 COMFORT-I stated, “Initiation of the Phase III registration trials for INCB18424’s use in myelofibrosis marks an important step forward in developing a new effective treatment for this under-served disease. Importantly, the primary and secondary endpoints in COMFORT-I and COMFORT-II are clinically relevant features of the disease that both physicians and patients are currently unable to overcome. I am optimistic that over time, the results from the INCB18424 myelofibrosis Phase III program will lead to important insights regarding the disease itself and the long-term value of treatment with a JAK1/JAK2 inhibitor.”

COMFORT-I Trial

**Overall Design:** COMFORT-I (also referred to as INCB18424-351) is a randomized (1:1), double-blind Phase III study comparing the efficacy and safety of INCB18424 to placebo in approximately 240 patients with PMF, PPV-MF or PET-MF. To be eligible for the study, patients must have a palpated spleen length of 5 cm or greater and be classified as intermediate 2 or high risk according to the International Working Group (IWG) criteria (Cervantes et al, 2008).

**Primary Efficacy Endpoint:** Proportion of patients achieving ≥35% reduction in spleen volume from baseline to week 24 as measured by MRI (or CT scan in applicable subjects).

**Key Secondary Efficacy Endpoints:** Durability of a ≥35% reduction from baseline in spleen volume among patients initially randomized to receive INCB18424 and the proportion of patients achieving a ≥50% reduction in their total symptom score from baseline to week 24 as measured by the modified Myelofibrosis Symptom Assessment Form (MFSAF) diary.

**Duration of Trial:** The double-blind portion of COMFORT-I is 24 weeks. Data are scheduled to be analyzed when the last patient has completed 24 weeks of treatment with either INCB18424 or placebo and at least 50% of patients remaining in the study have completed 36 weeks of treatment.

COMFORT-I is scheduled to continue until either INCB18424 receives marketing approval or when the last randomized patient remaining in the study has completed week 144 (36 months).

**Cross Over From Placebo to INCB18424:** When the last randomized subject has received 24 weeks of treatment with placebo, and at least 50% of patients remaining in the study have completed 36 weeks of treatment, and the primary data analysis is complete, the study is scheduled to be unblinded, and eligible patients randomized to placebo will have the opportunity to cross over and begin receiving INCB18424 open label. If a patient treated with placebo meets certain pre-determined criteria, he or she may be eligible to cross over and receive treatment with INCB18424 prior to week 24.
**About the Modified Myelofibrosis Symptom Assessment Form (MFSAF) Diary:**
A modified Myelofibrosis Symptom Assessment Form diary will be used to measure symptoms in COMFORT-I. The MFSAF diary was developed from work conducted by Ruben Mesa, M.D., Professor of Medicine, Mayo Clinic Arizona, et al to measure quality of life and symptomatic response to treatment in myelofibrosis: (*Leukemia Research*, Volume 33, Issue 9, Pages 1199-1203).

Dr. Mesa stated, “Quality of life in patients with myelofibrosis is severely compromised by debilitating symptoms including fatigue, night sweats, fever, weight loss, pruritus, and symptoms from frequently massive hepatosplenomegaly. Using an international internet-based survey of 458 patients with MF, we created a 20-item instrument, Myelofibrosis Symptom Assessment Form, which measured the symptoms reported by greater than 10% of MF patients. The results we generated from the survey were highly correlated with other validated instruments in cancer patients and judged comprehensive and understandable by patients. It is very gratifying to see the modified MFSAF being used in the INCB18424 COMFORT-I Phase III program.”

**COMFORT-II Trial**
COMFORT-II (also referred to as INCB18424-352) is a second Phase III trial being conducted in Europe. It is an open-label study designed to evaluate the efficacy, safety and tolerability of INCB18424 as compared to the best-available therapy in 150 patients with PMF, PPV-MF or PET-MF. COMFORT-II is expected to involve approximately 70 clinical sites in 10 European countries: Belgium, Austria, France, Italy, Germany, Sweden, the Netherlands, Spain, Switzerland and the U.K. The primary efficacy endpoint in COMFORT–II is the proportion of patients achieving at least 35% reduction in spleen volume from baseline to week 48. Enrollment in COMFORT II began in July of this year.

**About Myelofibrosis**
Myelofibrosis is a serious neoplastic condition for which there are no approved therapies in the U.S. It is 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. Myelofibrosis is part of a related group of hematological neoplasms called myeloproliferative disorders that includes myelofibrosis, polycythemia vera and essential thrombocythemia. Approximately 10 to 20% of patients with polycythemia vera and essential thrombocythemia progress to myelofibrosis. Myelofibrosis can also develop without a prior history of polycythemia vera and essential thrombocythemia.

**About Special Protocol Assessments**
The SPA is a process that allows for official FDA evaluation of the clinical protocols of a Phase III clinical trial intended to form the primary basis for an efficacy claim and provides trial sponsors with a binding written agreement that the design and analysis of the trial are adequate to support a marketing application submission if the trial is performed according to the SPA. Final marketing approval depends on the results of efficacy, the adverse event profile and on an evaluation of the benefit/risk of
treatment demonstrated in the Phase III trials. The SPA agreement may only be changed through a written agreement between the sponsor and the FDA, or if the FDA becomes aware of a substantial scientific issue essential to product efficacy or safety. For more information on Special Protocol Assessment, please visit: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm080571.pdf

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 website 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 the anticipated completion of the Phase III clinical trial in patients with myelofibrosis and timing of filing of a New Drug Application for INCB18424 assuming positive results are received, the expected times to begin enrollment of patients in COMFORT-I, the expected number of clinical sites and patients for COMFORT-I and the expected number of clinical sites and countries for COMFORT-II, 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 uncertainty of the regulatory approval processes, uncertainty regarding the timing of commencement of the COMFORT-I trial, Incyte's ability to enroll a sufficient number of patients for the COMFORT-I and COMFORT-II clinical trials in a timely manner or at all, unanticipated developments in the efficacy or safety of INCB18424, 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, 2009. Incyte disclaims any intent or obligation to update these forward-looking statements.

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