

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **July 21, 2009**

INCYTE CORPORATION

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction of
Incorporation)

0-27488
(Commission File Number)

94-3136539
(I.R.S. Employer
Identification No.)

**Experimental Station
Route 141 & Henry Clay Road
Building E336
Wilmington, DE**
(Address of principal executive offices)

19880
(Zip Code)

(302) 498-6700
(Registrant's telephone number,
including area code)

N/A
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On July 21, 2009, Incyte Corporation issued a press release announcing an update on its request for a Special Protocol Assessment with the U.S. Food and Drug Administration for INCB18424 as a treatment for myelofibrosis. A copy of the press release dated July 21, 2009 is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

- (d) Exhibits
- 99.1 Press release issued by Incyte Corporation dated July 21, 2009.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: July 21, 2009

By: _____ /s/ Patricia A. Schreck
Patricia A. Schreck
Executive Vice President and General Counsel



FOR IMMEDIATE RELEASE

Pamela M. Murphy
Vice President, Investor Relations & Corporate Communications
(302) 498-6944

**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 thrombocythemia 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 (**CO**ntr**OL**led **Myelo**Fibrosis Study with **OR**al JAK Inhibitor **T**reatment), 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."

1

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 ³ 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 ³ 35% reduction from baseline in spleen volume among patients initially randomized to receive INCB18424 and the proportion of patients achieving a ³ 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.

2

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.

Links to third-party websites or pages are provided for convenience only. Each website is subject to its own terms of use, and we encourage you to consult these policy statements. Incyte has no control over third party sites and does not endorse or recommend these sites, and expressly disclaims any responsibility for the accuracy of content or opinions set forth in any third party website or your use of that information.