

**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): **May 28, 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 May 28, 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 May 28, 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 May 28, 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: May 28, 2009

By: \_\_\_\_\_ /s/ David C. Hastings  
David C. Hastings  
Executive Vice President and  
Chief Financial Officer



**FOR IMMEDIATE RELEASE**

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

**Incyte Provides Update on Special Protocol Assessment for INCB18424 as a New Treatment for Myelofibrosis**  
**Announces Plan to Initiate a Phase III Registration Trial in Europe in June**

**Wilmington, DE — May 28, 2009** — Incyte Corporation (Nasdaq: INCY) announced today that based on recent input from the U.S. Food and Drug Administration (FDA) regarding Incyte's request for a Special Protocol Assessment (SPA) for INCB18424 for patients with primary myelofibrosis (PMF), post-polycythemia vera myelofibrosis (PPV-MF) and post-essential thrombocythemia myelofibrosis (PET-MF), it is clear that the most appropriate single primary endpoint for Incyte's U.S. Phase III trial is the proportion of treated patients achieving a 35% reduction in spleen volume as compared to patients receiving placebo.

Paul A. Friedman, M.D., President and CEO of Incyte, stated, "Because INCB18424 is a first-in-class compound and there has never been a registration trial for this disease conducted in the U.S., it has taken a couple of iterations on the SPA request to establish that reduction in spleen volume is the most appropriate primary endpoint to support approval of a new treatment for myelofibrosis."

Dr. Friedman added, "Although resubmitting our request will cause a modest delay in starting the Phase III study, we still anticipate completion of the study in a time frame that will allow for filing a New Drug Application in late 2010 or early 2011 assuming positive results are achieved. This time frame is consistent with prior guidance provided."

Based on the aforementioned interaction with the FDA, Incyte expects to begin enrollment of COMFORT-I (COntrolled MyeloFibrosis Study with ORal JAK Inhibitor Treatment) in August 2009.

The Phase III European trial, COMFORT-II, is scheduled to begin enrollment in June 2009. COMFORT-II 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. This trial is expected to involve approximately 70 clinical sites in 10 European countries and has been designed based on scientific advice from the European Medicines Agency. 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.

**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. 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/cder/guidance/3764fnl.htm>.

**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 II clinical trials 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 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 and COMFORT-II, 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, including uncertainty

regarding the nature and timing of the FDA's response to Incyte's revised request for SPA and the timing of submission of Incyte's revised request, uncertainty regarding the timing of commencement of the COMFORT-I trial based in part on uncertainty regarding the timing and nature of the FDA's response to Incyte's revised request for SPA, 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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