



FOR IMMEDIATE RELEASE

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Incyte Announces Positive Top-Line Results from COMFORT-I Pivotal Phase III Trial of INCB18424 in Myelofibrosis, a Debilitating, Life-Threatening Blood Cancer

- Trial meets primary and key secondary endpoints
- Safety and tolerability consistent with data from prior studies
- Full results to be submitted for presentation at the 2011 American Society of Clinical Oncology Annual Meeting
- New Drug Application submission on track for second quarter of 2011

Company to Host Conference Call Today at 5:00 p.m. ET

Wilmington, DE – December 20, 2010 – Incyte Corporation (Nasdaq:INCY) announced today positive top-line results from COMFORT-I, the pivotal Phase III clinical trial of INCB18424 (also known as INC424) in patients with myelofibrosis (MF) being conducted under a Food and Drug Administration (FDA) Special Protocol Assessment (SPA) Agreement. COMFORT-I (**CO**ntr**OL**lled **Myelo**Fibrosis Study with **OR**al JAK Inhibitor **T**reatment) is a double-blind, placebo-controlled Phase III trial involving 309 patients. The primary endpoint was the response rate defined as the percentage of patients achieving a 35% or greater reduction in spleen volume at 24 weeks as measured by magnetic resonance imaging, or computerized tomography, comparing the rates in patients receiving INCB18424 or placebo. The response rate was 42% in patients randomized to INCB18424 versus less than 1% of patients randomized to placebo; thus a high level of statistical significance ($p < 0.0001$) was achieved.

High levels of statistical significance were also achieved for the key secondary endpoints based on symptomatic improvement as measured by the modified Myelofibrosis Symptom Assessment Form Diary. Response rates among patients receiving INCB18424 were similar to those previously reported with INCB18424 in the Phase II trial while much lower response rates were reported for patients receiving placebo in COMFORT-I.

The safety profile of INCB18424 was consistent with previous studies, which included reversible thrombocytopenia and anemia.

Incyte intends to submit the data from COMFORT-I for presentation at the 2011 American Society of Clinical Oncology Annual Meeting.

Paul Friedman, M.D., President and CEO of Incyte stated, "These highly significant results from COMFORT-I are similar to what was seen in the Phase II trial recently published in the *New*

England Journal of Medicine. We look forward to continuing our work with the FDA and our investigators as we strive to make this new medicine available to patients with myelofibrosis as rapidly as possible. In this regard, we are proceeding with the preparation of a New Drug Application and believe INCB18424 has the potential to become the first FDA-approved treatment for this debilitating, life-threatening disease.”

“In addition to meeting the efficacy endpoints in this controlled trial, the safety and tolerability profile suggests that INCB18424 could become the first widely available medication to relieve the debilitating symptoms in patients with myelofibrosis,” added Richard Levy, M.D., Executive Vice President and Chief Drug Development and Medical Officer at Incyte.

Based on the SPA agreement, COMFORT-I is the only pivotal trial required for approval in the U.S. Data from a second Phase III trial, COMFORT-II, which is the pivotal trial for European Marketing Authorization, comparing INCB18424 to best available therapy, is being conducted by Novartis in Europe and is also expected to provide supportive data for approval and labeling in the U.S. Results of COMFORT-II are expected early next year. Incyte and Novartis announced a collaboration and license agreement in November 2009 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. Both the FDA and the European Medicines Agency have granted INCB18424 orphan drug status for MF.

About COMFORT-I and COMFORT-II

COMFORT-I is a randomized (1:1), double-blind Phase III trial comparing the efficacy and safety of INCB18424 to placebo in 309 patients with primary myelofibrosis (PMF), post-polycythemia vera myelofibrosis (PPV-MF) or post-essential thrombocythemia myelofibrosis (PET-MF) and involved over 100 clinical sites in the U.S., Australia and Canada. To be eligible for the study, patients had to 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) criteria¹. COMFORT-I is scheduled to continue until either INCB18424 receives marketing approval or the last randomized patient remaining in the study has completed week 144 (36 months).

COMFORT-II is a second Phase III trial being conducted by Novartis in Europe. It is a randomized (2:1), controlled, open-label study designed to evaluate the efficacy, safety and tolerability of INCB18424 as compared to the best-available therapy in patients with PMF, PPV-MF or PET-MF. COMFORT-II enrolled 219 patients and involves approximately 55 clinical sites in 9 European countries: Belgium, Austria, France, Italy, Germany, Sweden, the Netherlands, Spain 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.

Neither COMFORT-I nor COMFORT-II were powered to demonstrate differences in survival.

About Special Protocol Assessment (SPA)

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 written agreement that the design and analysis of the trial are adequate to support a New Drug Application (NDA) 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 trial. 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 the FDA web site at <http://www.FDA.gov>.

About Myelofibrosis (MF)

MF is an uncommon, life-threatening blood cancer characterized by bone marrow failure, enlarged spleen (splenomegaly), debilitating symptoms including fatigue, night sweats and pruritus, poor quality of life, and weight loss, as well as shortened survival². MF is one of the Philadelphia chromosome-negative myeloproliferative neoplasms (MPNs) which also includes polycythemia vera and essential thrombocythemia. Of the JAK-associated MPNs, MF carries the greatest risk of a poor prognosis, including transformation to fatal acute myelogenous leukemia, and there are currently no approved treatments for MF in the U.S.^{2,3}. Although allogeneic stem cell transplantation may cure MF, the procedure is associated with significant morbidity and mortality and is usually appropriate only in younger patients⁴.

About INCB18424

INCB18424 is an orally available JAK1 and JAK2 inhibitor that entered Phase I clinical testing in May 2007. The JAK family of enzymes are key players in a number of important biologic processes, including the regulation of immune function and the formation and development of blood cells⁵⁻¹⁰. A strong association exists between abnormal JAK signaling and the development of myelofibrosis, polycythemia vera, and essential thrombocythemia¹¹⁻¹⁵. The discovery of JAK mutations common to myelofibrosis, polycythemia vera and essential thrombocythemia, has linked them on a molecular level¹⁶. This finding, together with the fact that these patients tend to have elevated inflammatory cytokines that signal through JAK1 and JAK2, led Incyte to the discovery and development of INCB18424, a potent, selective inhibitor of the JAK1 and JAK2 tyrosine kinases^{17,18}.

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.

Conference Call Information

Incyte will host a conference call today at 5:00 p.m. ET. To access the conference call, please dial 877-407-8037 for domestic callers or 201-689-8037 for international callers. When prompted, provide the passcode, which is 363242.

If you are unable to participate, a replay of the conference call will be available for thirty days. The replay dial-in number for the U.S. is 877-660-6853 and dial-in number for international callers is 201-612-7415. To access the replay you will need the conference account number 278 and the ID number 363242.

Forward Looking Statements

Except for the historical information contained herein, the matters set forth in this press release, including statements regarding the intention to submit the data from COMFORT-I for presentation at the 2011 American Society of Clinical Oncology Annual Meeting, continuing our work with the FDA and our investigators as we strive to make this new medicine available to patients with myelofibrosis as rapidly as possible, proceeding with the preparation of a New Drug Application and our belief that INCB18424 has the potential to become the first FDA-approved treatment for this debilitating, life-threatening disease, that the safety and tolerability profile suggests that INCB18424 could become the first widely available medication to relieve the debilitating symptoms in patients with myelofibrosis, that the results of COMFORT-II are expected early next year and COMFORT-II is also expected to provide supportive data for approval and labeling in the U.S., and that COMFORT-I is scheduled to continue until either INCB18424 receives marketing approval or the last randomized patient remaining in the study has completed week 144 (36 months), 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, unanticipated developments in the efficacy or safety of INCB18424, the possibility that the outcomes for each of the planned clinical trials for INCB18424 may not be favorable, the possibility that regulatory authorities may require additional clinical trials in order to support registration of INCB18424 in any particular indication, the possibility that there may be other interpretations of the data produced in one or more of Incyte's clinical trials, the risk that regulatory authorities will require more extensive data for the INCB18424 NDA filing than currently expected, future competitive or other market factors that may adversely affect the commercial potential for 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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