Incyte's JAK Inhibitor Demonstrates Rapid and Marked Clinical Improvement in Rheumatoid Arthritis Patients

October 26, 2008

Complete Results from 28-day Phase IIa Clinical Trial Presented at the 2008 American College of Rheumatology Annual Scientific Meeting A Webcast and Conference Call to Discuss These Results Are Scheduled for Tonight at 10:30 P.M. Eastern Time / 7:30 P.M. Pacific Time

WILMINGTON, Del.--(BUSINESS WIRE)--Oct. 26, 2008--Incyte Corporation (Nasdaq:INCY) announced today the presentation of clinical results from a 28-day Phase IIa trial of INCB18424, its orally available janus kinase (JAK) inhibitor, in patients with rheumatoid arthritis (RA).

Results from the 50-patient placebo-controlled trial demonstrated that three of the four doses of INCB18424 evaluated (15 mg BID, 25 mg BID and 50 mg QD) produced impressive clinical benefits and all of the doses were well tolerated. American College of Rheumatology (ACR) 20, ACR50, ACR70 and ACR90 response rates in the three most effective dose groups ranged from 50% to 83%, 40% to 50%, 25% to 30%, 10% to 17% respectively, and were achieved in one month, with responses seen as early as one week (see data summary below). Although there have been no head-to-head comparator trials, ACR 20/50/70 response rates with existing injectable biologic agents in larger studies typically average 60%/40%/20%, respectively, after 3 to 6 months of therapy.

The results were presented today in an oral presentation by Larry Moreland, M.D., Margaret Jane Miller Endowed Professor of Arthritis Research, Chief, Division of Rheumatology and Clinical Immunology, University of Pittsburgh, and principal investigator of the study, during the "RA Treatment: Small Molecules and Gene Therapy" session at the 2008 American College of Rheumatology / Association of Rheumatology Health Professionals (ACR/ARHP) Annual Scientific Meeting.

Dr. Moreland stated, "Results from this initial Phase IIa trial suggest that INCB18424, a novel oral JAK inhibitor, has the potential to be at least as effective as currently available RA therapies, including the widely used injectable biologicals. I look forward to participating in the next phase of clinical trials and seeing this new class of potent oral anti-inflammatory agents with an exciting mechanism of action progress through clinical development."

Summary of Phase IIa Trial

Key Efficacy Results:

The patients in this study had highly active disease at baseline with tender and swollen joint counts averaging from 11-20 using a 28 joint count, and Disease Activity Scores (DAS) in the 6-7 range. Below is a summary of the ACR scores on day 28 and DAS28 scores using C-Reactive Protein (DAS28CRP) on day 28:

	(N)	ACR20	ACR50	ACR70	ACR90
		% (N)	% (N)	% (N)	% (N)
Placebo	9	33 (3)	11 (1)	0 (0)	0 (0)
5 mg BID	9	33 (3)	11 (1)	0 (0)	0 (0)
15 mg BID	12	83 (10)	50 (6)	25 (3)	17 (2)
25 mg BID	10	50 (5)	40 (4)	30 (3)	10 (1)
50 mg QD	10	60 (6)	50 (5)	30 (3)	10 (1)

The ACR 20/50/70 response rates for placebo and the 5 mg BID dose group were similar, 33% ACR20 and 11% ACR50. The response rates for the three higher doses, 15 mg BID, 25 mg BID and 50 mg QD, achieved ACR20 rates of 50% to 83%, ACR50 rates of 40% to 50%, ACR70 rates of 25% to 30% and ACR90 rates of 10% to 17%. All the individual components of the ACR assessments showed similar trends for improvement, including marked improvement in the Health Assessment Questionnaire, a measure of functional status which typically can take several months to show improvement.

	(N)	DAS28CRP less than 3.2	DAS28CRP less than 2.6
		% (N)	% (N)
Placebo	9	0 (0)	0 (0)
5 mg BID	9	0 (0)	0 (0)
15 mg BID	12	50 (6)	25 (3)
25 mg BID	10	30 (3)	10 (1)

50 mg QD	10	50 (5)	30 (3)

Patients who achieved a DAS28CRP score less than 3.2, which corresponds to mild disease, and less than 2.6, which corresponds to remission if sustained, were only seen in the three higher dose groups, 15 mg BID, 25 mg BID and 50 mg QD. In these three dose groups, the proportion of subjects achieving a DAS28CRP below 3.2 ranged from 30% to 50% of subjects, and the proportion achieving a score less than 2.6 ranged from 10% to 30% in 28 days.

Safety:

INCB18424 was safe and well tolerated. Adverse effects (AEs) were seen in similar frequency in patients receiving INCB18424 or placebo. In general, AEs were mild and self-limited during continued dosing. There were no changes in mean hemoglobin or platelet counts and mean neutrophil counts remained completely within the normal range even with the expected transient margination effects common to drugs that inhibit the activity of IL-6. There was one margination-induced grade 3 neutropenia which improved during continued dosing and rapidly resolved after the last dose (50 mg QD) and one reversible grade 3 thrombocytopenia in a patient with a history of recurrent immune-mediated thrombocytopenia (50 mg QD). In future studies, the rare patient with immune-mediated thrombocytopenia or other causes of recurrent thrombocytopenia will be excluded. There were no serious infections in any patient group. Minor infections were infrequent and similar in occurrence in the placebo and INCB18424 treated patients.

Trial Design:

This was a 28-day, double-blind, placebo-controlled study in patients with active RA as defined by six or more tender and four or more swollen joints and erythrocyte sedimentation rate (ESR) greater than 28 mm/h or C-reactive protein (CRP) greater than 15 mg/L. Patients in the trial could remain on stable doses of methotrexate, sulfasalazine, antimalarials and/or low dose prednisone. Patients could not have received treatment with biological agents or other DMARDs for at least 12 weeks. Patient assessments were conducted at weeks 1, 2 and 4.

Endpoints:

The study endpoints were safety, ACR20, ACR50, ACR70 scores, Disease Activity Score including a 28-joint count (DAS28), % with DAS28 less than3.2 and change in individual ACR assessments.

Future Phase IIb Trials Planned for INCB18424

Based on these 28-day Phase IIa results, two six-month Phase IIb trials using a similar range of doses are expected to begin in the fourth quarter of this year. The first trial is expected to involve eight treatment arms and 280 RA patients who are receiving disease modifying therapy but whose disease is not adequately controlled. The second trial is expected to include 140 patients previously treated with anti-TNF therapies for at least eight weeks.

About Rheumatoid Arthritis

Rheumatoid arthritis is an autoimmune disease, estimated to affect about 1% of the world's population. The disease is characterized by aberrant immune mechanisms that lead to joint inflammation and swelling with progressive destruction of joints. In addition to affecting the joints, RA can also affect connective tissue in the skin and organs of the body.

Current treatment of RA includes the use of non-steroidal anti-inflammatory drugs, disease-modifying anti-rheumatic drugs such as methotrexate, and the newer injectable biological response modifiers that target tumor necrosis factor alpha (TNF-a), a pro-inflammatory cytokine implicated in the pathogenesis of RA. None of these approaches to treatment is curative nor without serious adverse effects, especially in long-term use, and RA remains a disease for which there is still significant unmet clinical need.

About the Incyte JAK Inhibitor Program

There are four known JAK enzymes: JAK1, 2, 3 and TYK2. These enzymes are critical components of signaling mechanisms utilized by a number of cytokines and growth factors, including those that are elevated in RA patients. Pathways triggered by the JAKs are dysregulated in inflammation, myeloproliferative diseases, and other liquid and solid cancers.

INCB18424 is Incyte's lead internally developed JAK inhibitor. The compound is a potent JAK inhibitor that is greater than100-fold selective against a broad panel of kinases and is being developed as an oral treatment for RA, psoriasis (as a topical treatment), myelofibrosis, polycythemia vera, essential thrombocythemia, multiple myeloma, and hormone refractory prostate cancer.

Incyte has discovered multiple potent, selective and orally bioavailable JAK inhibitors from multiple distinct chemical scaffolds. In addition to INCB18424, a follow-on compound, INCB28050, has completed single- and multiple-dose Phase I trials and is expected to begin Phase IIb in the first half of 2009.

Webcast Information

Incyte is hosting a webcast and conference call tonight at 10:30 p.m Eastern Time / 7:30 p.m Pacific Time to discuss the clinical results presented at the 2008 ACR Annual Meeting.

The live listen-only webcast with slides of the presentation can be accessed on Incyte's website: http://investor.incyte.com/phoenix.zhtml?c=69764&p=irol-Calendar

Analysts and investors are also invited to participate in the conference call by calling the following toll free numbers:

Domestic Dial In Number: 877-407-8037

International Dial In Number: 201-689-8037

Conference ID #: 300810

If you are unable to participate, a replay of the webcast will be available on Incyte's website and can be accessed at www.incyte.com under Investor Relations, Events and Webcasts.

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 I and Phase II development for oncology, inflammation and diabetes. 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 with respect to the potential for Incyte's JAK inhibitor INCB18424 to be at least as effective as currently available RA therapies, the potential value of the JAK inhibitor program, plans to begin two six-month Phase IIb trials for INCB18424 and the expected design and timing of the trials and plans to begin a Phase IIb trial for INCB28050 in the first half of 2009 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 associated with drug development and clinical trials, the uncertainty of the FDA approval process, results of further research and development, the impact of competition and of technological advances and the ability of Incyte to compete against parties with greater financial or other resources, Incyte's ability to enroll a sufficient number of patients for its clinical trials, 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 June 30, 2008. Incyte disclaims any intent or obligation to update these forward-looking statements.

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