Incyte's Selective Oral JAK1 and JAK2 Inhibitor Demonstrates Positive Phase IIa Results in Patients with Active Rheumatoid Arthritis

November 10, 2010

Six-month Phase IIa clinical trial results presented at the 2010 ACR/ARHP Annual Scientific Meeting demonstrate that INCB28050 improved ACR scores in patients inadequately treated with DMARDS and patients previously treated with biologics

Webcast scheduled tonight at 8:00 pm ET

WILMINGTON, Del., Nov 10, 2010 (BUSINESS WIRE) -- Incyte Corporation (Nasdaq:INCY) announced the presentation of final six-month clinical data from the dose ranging, placebo-controlled Phase IIa trial of its orally available janus kinase (JAK) inhibitor INCB28050 in patients with active rheumatoid arthritis (RA). These results were presented today at the 2010 American College of Rheumatology / Association of Rheumatology Health Professionals (ACR/ARHP) Annual Scientific Meeting being held in Atlanta, November 7 to 11, 2010.

Results from the 125-patient Phase IIa trial demonstrated that all three doses of oral INCB28050 (4 mg QD, 7 mg QD and 10 mg QD) improved on the primary endpoint, the percent of patients achieving American College of Rheumatology (ACR) 20 improvement, over the full 24-week treatment period. Importantly, ACR responses improved between week 12 and week 24 achieving up to 72% for ACR20, 44% for ACR50 and 30% for ACR70 at week 24. Results seen at 12 weeks for placebo were 32% for ACR20, 13% for ACR50 and 3% for ACR70, and for patients treated with INCB28050 the results were up to 59% for ACR20, 35% for ACR50 and 16% for ACR70.

Evidence of improvement was seen as early as the first assessment at two weeks. Responses were similar in both biologic-experienced and biologic-naïve patients and adverse events for all three doses were predominantly mild-to-moderate with frequencies similar to placebo.

"Results from the Phase IIa trial with INCB28050, an oral JAK1 and JAK2 inhibitor are encouraging, suggesting that the compound has the potential to become a welcome addition to the current armamentarium of available RA therapies. There is a clear unmet need for new oral RA therapies and we look forward to seeing INCB28050 progress through clinical development," stated Maria Greenwald, M.D., F.A.C.R., Palm Desert, California, the presenting investigator of the Phase IIa trial results.

Summary of Phase IIa Clinical Results (Study 28050-201)

ACR20, ACR50 and ACR70 response rates for the three once daily dose groups and placebo patients at 12 weeks and 24 weeks are described below:

ACR Response Rates

Modified Intent to Treat Total Population

	Placebo [1] (n=31)	4 mg (n=31)	7 mg (n=32)	10 mg (n=30)
ACR20				
Wk12	32%	52%	59%	53%
Wk24		67%	67%	72%
ACR50				
Wk12	13%	35%	31%	30%
Wk24		33%	37%	44%
ACR70				
Wk12	3%	16%	9%	10%
Wk24		26%	30%	28%

[1] After 12 weeks of treatment, placebo-treated patients were randomized to receive either 7 mg QD or 10 mg QD

In addition to the ACR response rates, patients who achieved Disease Activity Scores using C-reactive protein (DAS-CRP) of less than 3.2, which corresponds to mild disease, and less than 2.6, which corresponds to remission, also improved from week 12 through week 24. At 24 weeks the remission rates for DAS-CRP<2.6 ranged from 30% to 48%.

DAS-CRP Scores

	Placebo (n=31)	4 mg (n=31)	7 mg (n=32)	10 mg (n=30)
DAS-CRP<3.2				

Wk 12	26%	45%	34%	33%
Wk 24		48%	53%	65%
DAS-CRP<2.6				
Wk 12	16%	23%	25%	17%
Wk 24		30%	40%	48%

Safety

The most frequently reported adverse events during the placebo-controlled period were headache, upper respiratory tract infection, and diarrhea. Adverse events were predominantly mild-to-moderate with frequencies similar to placebo. There appeared to be no relationship between dose and total frequency of reported adverse events, with exception of reports of anemia. There were dose-related decreases in mean hemoglobin ranging from approximately 2% to 8%. Un-complicated cases of herpes zoster (shingles) were observed. HDL and LDL increased with a trend for improvement in the HDL to LDL ratio while CRP levels decreased.

Trial Design

Study 28050-201, a randomized, double-blind, placebo-controlled, dose-ranging trial, involved 125 patients with active RA with an inadequate response to any disease modifying anti-rheumatic drug (DMARD) therapy including biologics. The duration of the study was six months with the primary endpoint assessed at three months. Eligible patients were randomly assigned to one of three doses (4, 7 or 10 mg QD) of INCB28050 or placebo. At week 12, placebo patients crossed over to 7 mg QD or 10 mg QD.

Primary Outcome Measures:

- Safety and tolerability of INCB28050 as measured by adverse events, vital signs, clinical laboratory tests and ECGs at three months
- Efficacy as determined by percent of patients achieving ACR20 improvement at three months

Secondary Outcome Measures:

- Safety and tolerability of INCB28050 as measured by adverse events, vital signs, clinical laboratory tests and ECGs at six months
- Efficacy as determined by percent of patients achieving ACR20, 50, 70 and 90 improvement at six months

About Rheumatoid Arthritis

Rheumatoid arthritis (RA) 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, a pro-inflammatory cytokine implicated in the pathogenesis of RA. None of these approaches to treatment is curative and therefore a need remains for new safe and effective treatment options for patients with RA.

Webcast

Incyte is hosting a meeting to discuss the Phase IIa data for INCB28050 presented at ACR. The discussion will feature Maria Greenwald, M.D., F.A.C.R., Palm Desert, California, the presenting investigator of the these results, and Richard Levy, M.D., Executive Vice President, Chief Drug Development and Medical Officer, Incyte. A webcast of the event is scheduled to begin at 8:00 p.m. ET on Wednesday, November 10, 2010 and can be accessed using the following link: www.incyte.com under Investor Relations, Events and Webcasts.

A replay of this event will also be available and can be accessed at: www.incyte.com.

About JAK Inhibition

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. Cytokines such as interleukin-6, -12, and -23 signal through the JAK pathway and have been clinically validated as therapeutic targets in inflammatory diseases. Additional JAK-dependent cytokines have also been implicated in a number of inflammatory and autoimmune diseases suggesting that JAK inhibitors may be useful for the treatment of a broad range of inflammatory conditions.

About INCB28050 (LY3009104)

INCB28050 is an orally-available, potent and selective JAK1 and JAK2 inhibitor that is currently in Phase IIb development as a treatment for rheumatoid arthritis.

In December 2009, Incyte and Eli Lilly and Company (NYSE: LLY) (Lilly) announced an exclusive worldwide license and collaboration agreement for the development and commercialization of INCB28050 and certain follow-on compounds, for inflammatory and autoimmune diseases. Under the terms of this agreement, Lilly has responsibility for future clinical trials and INCB28050 is now referred to as LY3009104.

Lilly recently initiated a Phase IIb dose-ranging study expected to involve 270 patients with active rheumatoid arthritis that is now open to enrollment: clinicaltrials.gov/ct2/show/NCT01185353?term=INCB028050&rank=2.

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.

Forward-Looking Statements

Except for the historical information contained herein, the matters set forth in this press release, including statements that the results from the Phase IIa trial suggest that INCB28050, an oral JAK1 and JAK2 inhibitor, has the potential to be a welcome addition to the current armamentarium of available RA therapies and the expected number of patients in the Phase IIb clinical trial, 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 ability to enroll a sufficient number of patients, unanticipated developments in the efficacy or safety of INCB28050, 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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