

Positive Results Presented from Proof-of-Concept Phase II Clinical Trial of Incyte's Oral JAK1 Inhibitor in Patients with Active Rheumatoid Arthritis

October 28, 2013

- In results presented at the 2013 ACR/ARHP Annual Scientific Meeting, INCB39110 improved multiple rheumatoid arthritis efficacy scores as compared to placebo over 12 weeks of therapy
- INCB39110 was generally well-tolerated without evidence of myelosuppression or immunosuppression

SAN DIEGO--(BUSINESS WIRE)--Oct. 28, 2013-- Incyte Corporation (Nasdaq: INCY) announced results from a 12-week, placebo-controlled, dose-escalation Phase II proof-of-concept clinical trial involving 60 patients with active rheumatoid arthritis for its proprietary oral JAK1 inhibitor. These results were presented today at the 2013 American College of Rheumatology / Association of Rheumatology Health Professionals (ACR/ARHP) Annual Scientific Meeting being held in San Diego, CA, from Oct. 25 to 30, 2013.

"Along with our recently presented data with INCB39110 in psoriasis, results from this study in rheumatoid arthritis demonstrate the potential of JAK1 inhibition in inflammatory indications," stated Richard S. Levy, Incyte's Executive Vice President and Chief Drug Development and Medical Officer.

In this initial Phase II trial, 12 weeks of treatment with INCB39110 showed efficacy at all doses as measured by ACR 20, ACR 50, ACR 70, and DAS 28 as compared to placebo. Clinical benefit was observed as early as one week of treatment, and the highest dose tested, once-daily 600 mg, appeared to be the most effective dose. Below is a summary of the key efficacy endpoints evaluated at 12 weeks:

	INCB039110				
	Placebo N=12	100 mg BID N=13	300 mg QD N=12	200 mg BID N=13	600 mg QD N=11
ACR 20, n (%)	4 (33)	7 (54)	6 (50)	6 (46)	10 (91)
ACR 50, n (%)	2 (17)	6 (46)	5 (42)	5 (39)	7 (64)
ACR 70, n (%)	1 (8)	4 (31)	1 (8)	2 (15)	6 (55)

	INCB039110				
	Placebo N=12	100 mg BID N=13	300 mg QD N=12	200 mg BID N=13	600 mg QD N=11
DAS 28 ESR Mean score*	5.4(-1.2)	4.0 (-2.7)	3.9 (-2.5)	4.3 (-2.4)	3.1 (-3.2)
DAS 28 ESR < 2.6, n (%)	0 (0)	1 (8)	2 (17)	3 (23)	3 (27)
DAS 28 CRP Mean score*	4.8(-1.1)	3.3 (-2.7)	3.2 (-2.4)	3.6 (-2.2)	2.7 (-2.9)
DAS 28 CRP < 2.6, n (%)	0 (0)	4 (31)	3 (25)	2 (15)	5 (46)

* Mean score at week 12 (change from baseline)

Safety

While larger patient populations and longer term exposure are needed to fully explore the safety profile of INCB39110, at all doses evaluated in this trial, the compound was generally well-tolerated without evidence of myelosuppression or immunosuppression. Additionally, all treatment-emergent AEs were mild to moderate in intensity; there were no drug related serious adverse events, and no serious related or unrelated infections. Mean values for evaluated safety measures, including hemoglobin, neutrophil count, platelet count and lymphocyte count, remained stable and within normal range across the 12 weeks of the study. Mild increases were observed in ALT and AST during the first weeks of treatment. No patient developed a Grade 3 or Grade 4 abnormality or had an associated increase in bilirubin, which is consistent with enzyme induction. Increases in LDL and HDL were also noted, consistent with the expected effects of reduction of IL-6 signaling, without a significant change in the HDL/LDL ratio.

To access the presentation: [ACR 2013 - INCB39110 Presentation](#)

About the Study: A Randomized, Dose-Ranging, Placebo-Controlled, 12-Week Study of INCB39110, a Selective Janus kinase-1 Inhibitor, in Patients with Active Rheumatoid Arthritis

This Phase II double-blind, placebo-controlled, multicenter study was conducted in the United States and involved 60 subjects with active rheumatoid arthritis as defined by 1987 ACR criteria (≥ 4 swollen joints, ≥ 6 tender joints, CRP ≥ 6 mg/L). Eligible patients were randomized to receive placebo or INCB39110 at oral doses of 100 mg twice daily, 300 mg once daily, 200 mg twice daily or 600 mg once daily for 12 weeks. Patients who were on stable

doses of methotrexate continued at the same dose during study, and patients on stable anti-malarials for ≥ 6 months or stable sulfasalazine for ≥ 8 weeks were permitted to continue on their existing therapy. Patients previously exposed to leflunomide or biologic DMARDs for more than 12 weeks prior to screening were also eligible.

The primary endpoint of the study was the proportion of patients who achieved an ACR 20 at week 12. Secondary endpoints at week 12 included the proportion of patients who achieved ACR 50 or ACR 70, the mean change from baseline in DAS 28 score, and the proportion of patients who achieved a DAS 28 score of < 2.6 .

About INCB39110

INCB39110 is the most advanced compound within Incyte's portfolio of selective JAK1 inhibitors and is being evaluated in Phase II proof-of-concept trials in psoriasis, rheumatoid arthritis and myelofibrosis and an initial Phase I/II safety study in combination with gemcitabine and nab-paclitaxel in patients with advanced solid tumors to help define its clinical efficacy and safety profile, understand potential points of differentiation between JAK1 and JAK1/JAK2 inhibition and determine the most appropriate path forward for further development.

About Incyte

Incyte Corporation is a Wilmington, Delaware-based biopharmaceutical company focused on the discovery, development and commercialization of proprietary small molecule drugs for oncology and inflammation. For additional information on Incyte, please visit the Company's website at www.incyte.com.

Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including without limitation statements with respect to the potential efficacy and safety and therapeutic potential of INCB39110 and the potential of JAK1 inhibition in inflammatory indications, contain predictions and estimates and are 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 based on Incyte's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to the efficacy or safety of INCB39110, the results of further research and development, other market, economic or strategic factors and technological advances, 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, 2013. Incyte disclaims any intent or obligation to update these forward-looking statements.



Source: Incyte Corporation

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