Reverset Data Presented at the 11th Annual Conference on Retroviruses and Opportunistic Infections Demonstrate Potent Antiviral Effects in Treatment-Naive HIV Patients

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SAN FRANCISCO--(BUSINESS WIRE)--Feb. 11, 2004--Incyte Corporation (Nasdaq:INCY) and Pharmasset, Inc., its strategic collaborative and licensing partner for Reverset(TM), announced today the results of a 10-day Phase II dose-escalating, placebo-controlled trial designed to evaluate the anti-viral effects and safety of Reverset as monotherapy in 30 treatment-naive human immunodeficiency virus (HIV)-infected patients. The mean reduction in viral load for all treated patients ranged from 1.67 log10 copies/mL to 1.77 log10 copies/mL. The Phase II study involved three, once a day, dose levels: 50 mg, 100 mg and 200 mg, and demonstrated that Reverset was well-tolerated at all doses over the 10-day trial period. The results were presented today by Robert Murphy, M.D., Professor of Medicine, Northwestern University, at the 11th Annual Conference on Retroviruses and Opportunistic Infections.

Reverset is an investigational nucleoside-analogue reverse transcriptase inhibitor (NRTI) that is being developed as a once-a-day oral therapy for use in combination with other antiretroviral drugs for patients with HIV infections. Reverset is not yet approved for commercial use in any country.

Dr. Murphy stated, "The results from this study demonstrate that Reverset was well-tolerated at all three doses over the 10-day trial and active as monotherapy in treatment-naive individuals. Based on the potent antiviral activity we see with this compound and the plasma concentrations achieved in this first Phase II trial, I believe Reverset has the potential to inhibit many clinically prevalent resistant strains of HIV, including mutations that confer resistance to each of the currently approved NRTIs. As there are a growing number of patients who have become resistant to existing NRTIs, Reverset may provide a much needed alternative."

A second Phase II trial using Reverset in combination with other antiretroviral agents in 180 treatment-experienced HIV-infected individuals is expected to begin later in 2004 and will be conducted by Incyte, under the direction of a joint development steering committee with Pharmasset.

About This Study (Study 202)

Study 202 was a Phase II dose-escalating, placebo-controlled trial involving 30 treatment-naive HIV-infected patients with CD4 cell counts greater than 50 cells/mm3 and plasma HIV-1 RNA levels greater than 5,000 copies/ml. Patients received 10 days of dosing with Reverset using the 50 mg daily, 100 mg daily or 200 mg daily dose or placebo. In each dose cohort, 8 patients received Reverset and 2 patients received placebo.

The mean decrease in viral load among this population of treatment-naive HIV-infected patients was 1.67 log10, 1.74 log10 and 1.77 log10 for the 50 mg, 100 mg and 200 mg daily doses, respectively. Mean Day 10 plasma Cmax levels were 2.3 micromolar M, 5.4 micromolar M and 9.8 micromolar M for the 50 mg, 100 mg and 200 mg daily doses, respectively.

All doses were well tolerated and no dose-limiting toxicity was identified. The most common adverse experiences with Reverset were cold symptoms 46% (placebo 33%), headache 33% (placebo 33%), and tiredness 17% (placebo 17%).

Plasma PK values were linear with dose on days 1 and 10 of dosing. The Cmax values at all doses exceeded the in vitro IC90 for wild type HIV-1 and signature mutations for 3TC and AZT resistance and the Cmax at the 200 mg doses (9.8 + 2.9 micromolar M) also exceeded the IC90 for HIV-1 containing the K65R mutation. Because the plasma Cmax has been shown to be an important determinant of the active intracellular triphosphate form of the drug, these data suggest that Reverset has the potential to inhibit replication of HIV containing a wide variety of mutations that confer resistance to each of the currently approved NRTIs.

About the Incyte/Pharmasset Collaboration

In September 2003 Incyte and Pharmasset entered into a collaborative licensing agreement to develop and commercialize Reverset. Under the terms of the agreement, Incyte paid Pharmasset an upfront payment and will also pay Pharmasset performance milestone payments and future royalties on net sales in exchange for exclusive rights to develop, manufacture and market the drug in the U.S., Europe and certain other markets. Pharmasset retained marketing and commercialization rights in certain territories, including Mexico, Central and South America, Africa, the Middle East, Korea and China.

Conference Call Information

Incyte will host a conference call on Thursday, February 12, 2004 at 8:30 a.m. ET to discuss the news contained in this release. Robert Murphy, M.D, Professor of Medicine, Northwestern University, who presented the Phase II data at the 11th Annual Conference on Retroviruses and Opportunistic Infections, will participate in the call. The domestic dial-in number is 877-692-2592 and the international dial-in number is 973-582-2700. The conference ID # is 4474023.

Slides accompanying the call, as well as a webcast of the audio portion of the call, will be webcast live on CCBN and can be accessed at: www.incyte.com/webcasts.

If you are unable to participate, a replay of the conference call will be available through March 1, 2004 (12:00 midnight ET). The replay dial-in number for the U.S. is 877-519-4471 and dial-in number for international callers is 973-341-3080. The replay pin number is 4474023 or access the replay on Incyte's website.

About Incyte

Incyte is a Wilmington, Delaware-based drug discovery and development company with a growing pipeline of novel small molecule drugs to treat HIV, inflammation, cancer and diabetes. The company's most advanced product candidate, Reverset, is an oral, once-a-day therapy in Phase II clinical trials to treat patients with HIV infections. Currently, Incyte has four drug discovery programs underway, an extensive intellectual property portfolio and a proteomic information product line based in Beverly, Massachusetts.

Forward-Looking Statements

Except for the historical information contained herein, the matters set forth in this press release, including statements as to the therapeutic potential of Reverset, whether Reverset will provide an alternative to other drugs, and the expected initiation of further clinical trials, 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 subject to risks and uncertainties that may cause actual results to differ materially, including the high degree of risk associated with drug development, the risk that additional clinical trials may be unsuccessful or insufficient to meet applicable regulatory standards, results of further research, the impact of competition and of technical advances, and other risks detailed from time to time in Incyte's Securities and Exchange Commission reports, including its Quarterly Report on Form 10-Q for the quarter ended September 30, 2003. Incyte disclaims any intent or obligation to update these forward-looking statements.

CONTACT:
Incyte Corporation, Wilmington
Pamela M. Murphy, 302-498-6944
pmurphy@incyte.com

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