Results of Phase IIa Study Show That Reverset Has Potential to Reduce HIV Viral Load in Treatment-Experienced Patients

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WASHINGTON--(BUSINESS WIRE)--Oct. 31, 2004--Incyte Corporation(NASDAQ:INCY):

Additional analysis of results of a 10 patient 10-day phase IIa study presented at ICAAC also suggest Reverset is effective for patients with viral mutations often seen in treatment with currently available nucleoside-analogue reverse transcriptase inhibitors

Incyte Corporation (Nasdaq:INCY) announced that patients with HIV who were failing antiretroviral therapy showed a reduction in viral load following treatment with Reverset(TM), a nucleoside-analogue reverse transcriptase inhibitor (NRTI), according to the results from a fourth cohort of 10 treatment-experienced patients in a phase IIa clinical trial conducted jointly by Incyte and Pharmasset, Inc. Seven of the eight patients treated with Reverset demonstrated a clinically significant reduction in viral load. The results were presented today by Robert Murphy, M.D., Professor of Medicine, Northwestern University, in an oral presentation at the 44th International Conference on Antimicrobial Agents and Chemotherapy (ICAAC).

Initial results from this study, known as Study 202, which involved 30 treatment-naive and 10 treatment-experienced HIV patients, were presented at the XV International AIDS Conference in Bangkok earlier in 2004. The data presented today at ICAAC included additional analysis of findings related to several patient sub-groups within the population of 10 treatment-experienced subjects. In the 10-day study involving the 10 treatment-experienced patients, eight were treated with a 200 mg once-a-day dose of Reverset and two received placebo with their regimen. The findings from within this sub-group suggest that Reverset may be an effective therapeutic option for patients infected with HIV containing specific viral mutations often seen in treatment with currently available NRTI therapies.

"Resistance to therapy remains an ongoing problem for HIV patients and the physicians who treat them. These findings indicate that Reverset may have important applications for the population of people living with HIV who develop resistance to other antiretroviral therapies. Incyte is currently enrolling a phase IIb trial, known as Study 203, involving 180 treatment-experienced HIV patients who will be treated with Reverset in combination with other antiviral agents," stated Dr. Murphy.

Summary of Study 202 Results in Treatment-Experienced HIV Patients

In addition to the overall mean reduction in viral load of 0.8 log copies/mL among the eight Reverset-treated patients, analysis of the study findings presented by Dr. Murphy also showed, for the first time, that six subjects receiving or failing therapy with 3TC (Epivir(R)), and five subjects receiving or failing treatment with tenofovir (Viread(R)) achieved a mean viral load reduction of at least 0.7 log copies/mL following treatment with Reverset. Additionally, four of the eight Reverset-treated patients had HIV containing three or more thymidine analogue mutations. The mean decrease in viral load in these four subjects exceeded 0.4 log copies/mL, including data from one subject who did not respond. No subject in this study had HIV bearing the K65R mutation that is sometimes associated with tenofovir treatment failure, although two subjects had HIV with M41L and L210W mutations that also confer resistance to tenofovir. Additionally, no new resistance mutations developed during the 10 days of treatment with Reverset.

Dr. Murphy added, "While it is premature to draw firm conclusions based on the number of subjects in this preliminary study, the data indicate that Reverset has the potential to be used successfully in combination with other widely-used therapies. Additionally these preliminary data are consistent with laboratory studies which have indicated that Reverset has a unique resistance profile that will be active in patients when HIV becomes resistant to commonly used NRTI drugs."

Reverset was well-tolerated in all patients with no significant adverse effects observed. The most frequently reported adverse events in the 32 subjects who received Reverset in all four cohorts, including the previously presented treatment-naive subjects, were headache (31%, placebo 25%), cold symptoms (28%, placebo 25%) and neutropenia (19%, placebo 25%). No adverse event occurred statistically more frequently in patients treated with Reverset versus placebo.

Study 203 is currently enrolling patients at clinical sites in the United States, Germany and France. For more information about Study 203, patients and physicians can contact Incyte's clinical department at clinical.trials@incyte.com. Reverset is not yet approved for commercial use in any country. If results from the phase IIb trial are acceptable, Incyte plans to begin two pivotal phase III studies for Reverset in the second half of 2005.

To access a copy of Dr. Murphy's presentation go to: www.incyte.com

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.

About Incyte

Incyte Corporation is a Wilmington, Delaware based drug discovery and development company with a pipeline of oral compounds to treat HIV, inflammation, cancer and diabetes. The company's most advanced product candidate, Reverset(TM), is an oral, once-a-day therapy in phase II clinical trials to treat patients with HIV infections. The company's lead internal compound, INCB3284, is a proprietary, oral CCR2 antagonist in phase I development that may have therapeutic value in a number of chronic inflammatory diseases. Incyte has several other early drug discovery programs underway and a proteomic information business based in Beverly, Massachusetts.

About Pharmasset

Pharmasset, Inc., is an emerging pharmaceutical company committed to the discovery, development, and commercialization of novel antiviral drugs. The company leverages its expertise in nucleoside chemistry to develop therapeutics to combat infections caused by drug-resistant human immunodeficiency virus (HIV) and hepatitis viruses. Pharmasset has two drugs in Phase 2 clinical trials, Reverset(TM) and Racivir(R), and several other antiviral compounds in advanced preclinical studies.

In September 2003, Pharmasset entered into a collaborative licensing agreement with Incyte Corporation for the development and commercialization of Reverset in certain territories. In October 2004, Pharmasset entered into a collaboration agreement with Hoffmann-La Roche for the development and commercialization of PSI-6130 for the treatment of Hepatitis C. Pharmasset retains proprietary development and commercialization rights to the balance of its clinical and preclinical pipeline.

Pharmasset's expanding portfolio of antiviral therapeutics aims to improve the lives of individuals around the world.

Forward-Looking Statements

Except for the historical information contained herein, the matters set forth in this press release, including statements as to the expected utility of Incyte's product candidates, the potential benefits and value of Reverset as a treatment for treatment-naive patients or treatment-experienced patients, serious adverse events, development of resistance mutations, the results of Study 202 of Reverset, the expected enrollment of patients in Study 203 and plans for commencement of phase III 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 possibility that the results of the phase IIb clinical trials will not confirm the potential shown by the results of the phase IIa clinical trial reported in this press release, 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 June 30, 2004. Incyte disclaims any intent or obligation to update these forward-looking statements.

Epivir(R) is a registered trademark of Glaxo Group Limited

Viread(R) is a registered trademark of Gilead Sciences, Inc.

CONTACT:
Incyte Corporation
Pamela M. Murphy, 302-498-6944

SOURCE: Incyte Corporation