Phase IIa Study Results Demonstrate that Once-Daily 200 mg Dosing of INCB9471 Provided Potent and Prolonged Antiviral Activity in HIV-Infected Patients

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Results Suggest that INCB9471 Has the Potential to Provide Advantages over Other CCR5 Antagonists in Development

SYDNEY, Australia, Jul 24, 2007 (BUSINESS WIRE) -- Results from a 14-day Phase IIa clinical trial, presented today at the 4th International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention, demonstrate that INCB9471, an investigational drug for the treatment of HIV-1, the retrovirus that causes the acquired immunodeficiency syndrome, AIDS, provided a significant decline in viral load when used as monotherapy in 19 HIV-infected subjects, including ten treatment-naive and nine treatment-experienced patients not currently on antiviral therapies.

INCB9471 is a novel, orally available CCR5 antagonist that is part of a new class of drugs to treat HIV/AIDS. CCR5 antagonists work through a different mechanism of action than currently marketed oral antiviral drugs. Rather than fighting HIV inside a patient's white blood cells, CCR5 antagonists prevent the virus from entering uninfected cells by blocking its predominant entry route, the CCR5 co-receptor.

Results from this 14-day placebo-controlled Phase IIa study, which involved a total of 23 HIV-infected patients, demonstrated that the 200 mg once-daily dose of INCB9471 provided potent and prolonged antiviral effects in HIV patients with R5-tropic virus. Patients receiving INCB9471 achieved a mean 1.72 log10 viral load drop at day 14. The nadir in mean viral load decline was 1.81 log10 and occurred at day 16. Consistent with the long half-life of INCB9471 of 60 hours, at day 28, two weeks after their last dose, treated patients continued to show evidence of viral suppression with a mean 0.81 log10 reduction in viral load relative to baseline. INCB9471 was also extremely well-tolerated in this initial Phase IIa trial.

Calvin Cohen, M.D., M.S., the presenting principal clinical investigator and Research Director for both Harvard Vanguard Medical Associates and Community Research Initiative of New England, stated, "With its impressive and sustained antiviral effects, its ability to be taken as a once-a-day therapy without ritonavir-boosting and its potential to be combined with other once-daily antiviral therapies, INCB9471 has the potential to provide clinically relevant advantages over other CCR5 antagonists in development."

Dr. Cohen added, "I believe these data, along with data from other CCR5 antagonists, strongly suggest that this new class of drugs has the potential to provide an important advance for how we treat HIV patients."

Based on the results from this study, further clinical development of INCB9471 is warranted. Additional once-daily doses of INCB9471 are currently being evaluated to support initiation of two six-month Phase IIb studies.

About this Study

The Phase IIa placebo-controlled trial was designed to evaluate the safety, tolerability, pharmacokinetics and antiviral activity of 200 mg once-daily dose of INCB9471 as monotherapy in HIV-infected subjects harboring R5-tropic virus. HIV enters a cell by first binding to the CD4 receptor. After a conformational change, it then binds to either the CCR5 (R5) or CXCR4 (X4) co-receptor. The study involved 23 HIV-infected patients who were either treatment-naive or treatment-experienced who had not received antiretroviral treatments for a minimum of three months. Nineteen of the subjects received INCB9471, ten were treatment-naive and nine were treatment-experienced; four patients received placebo, two were treatment-naive and two were treatment-experienced.

Summary of Findings

Safety: INCB9471 was safe and well tolerated with no clinically significant chemistry, hematology or ECG changes as compared to placebo patients.

Pharmacokinetics: INCB9471 exhibited a long plasma half-life of 60 hours that is expected to provide more effective suppression of the virus even if patients occasionally miss a dose.

Efficacy: Subjects receiving INCB9471 showed rapid and prolonged reduction in viral load with a mean maximal decline of 1.81 log10 at day 16. Consistent with the long plasma half-life of INCB9471, viral load continued to be suppressed well beyond the 14-day dosing period with a mean 0.81 log10 decline in viral load observed at day 28. The HIV treatment-naive and HIV treatment-experienced patients who received INCB9471 had comparable reductions in viral load.

CD4+ cell counts were stable or slightly increased over the 14-day course of therapy in all treated patients.

Tropism: Tropism assays were conducted at screening, baseline, day 7 or day 14, and at day 28. Two of the 19 treated patients showed a change in tropism from pure R5 utilizing virus to a mixture of R5 and X4 utilizing virus. Clonal tropism and sequencing data suggest that these dual/mixed virus populations likely reflect pre-existing viral variants. Both patients showed reversion to R5 tropic virus after day 28. These results are similar to what has been observed with other CCR5 antagonists.

A copy of the presentation can be accessed using the following link: http://investor.incyte.com/phoenix.zhtml?c=69764&p=irol-presentations

About Incyte

Incyte Corporation (NASDAQ:INCY) is a Wilmington, Delaware-based drug discovery and development company focused on developing proprietary small molecule drugs to treat serious unmet medical needs. Incyte has a pipeline with programs in HIV, diabetes, 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 with respect to the potential for INCB9471 to be combined with other once-daily antiviral therapies and to provide clinically relevant advantages over other CCR5 antagonists in development, the potential for the new class of drugs to provide an important advance for how HIV patients are treated, expectations regarding the initiation Phase IIb studies of INCB9471, and the efficacy and potential benefits of INCB9471, 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, 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 March 31, 2007. Incyte disclaims any intent or obligation to update these forward-looking statements.

SOURCE: Incyte Corporation

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