Incyte Begins Phase I Study of INCB13739 as a New Treatment for Type 2 Diabetes

June 7, 2006

WILMINGTON, Del.--(BUSINESS WIRE)--June 7, 2006--Incyte Corporation (Nasdaq:INCY) today announced that it has initiated a Phase I clinical trial of INCB13739, an orally available small molecule inhibitor of 11beta-HSD1 (11-beta hydroxysteroid dehydrogenase type 1). 11beta-HSD1 is an enzyme that appears to be critical to the development of type 2 diabetes.

11beta-HSD1 converts inactive cortisone into the active glucocorticoid, cortisol, a natural antagonist of insulin action. Human clinical studies have long suggested an active role for cortisol in the pathogenesis of human type 2 diabetes, and recent data from preclinical studies have revealed that 11beta-HSD1 and local glucocorticoid production play a critical role in mediating the initiation of insulin resistance and progression to diabetes. Therefore, selective inhibitors of 11beta-HSD1 may provide a new class of drugs to treat type 2 diabetes as well as conditions often associated with this disease, such as dyslipidemia, atherosclerosis, and coronary heart disease.

The Phase I trial is a double-blind, placebo-controlled, single and multiple dose-rising study designed to assess the safety and pharmacokinetics of INCB13739 in healthy volunteers. The Phase I program will also evaluate the ability of INCB13739 to inhibit 11beta-HSD1 activity in adipose tissue and liver of high body mass index (BMI) individuals. Preclinical studies have shown that 11beta-HSD1 activity in these two tissues may be a primary driver of insulin resistance and diabetes.

Provided the compound is safe, we expect to initiate one-month Phase IIa trials in type 2 diabetes patients later this year which will allow us to evaluate the effect of this compound on multiple disease parameters including glucose production and insulin sensitivity.

About 11beta-HSD1

11beta-HSD1 is an enzyme that converts cortisone into the potent biologically active hormone cortisol. This conversion occurs intra-cellularly within several key metabolic tissues including the liver, adipose, muscle and pancreas. Importantly, preclinical studies have shown that the enzyme does not significantly affect neuroendocrine control of circulating cortisol, but rather provides a mechanism to specifically increase local glucocorticoid exposure within cells in a tissue-specific manner. Unlike the hormone insulin, which is produced by beta-cells in the pancreas and maintains normal blood glucose levels, cortisol elevates blood glucose levels by driving glucose production in the liver, and inhibiting the uptake and disposal of glucose in muscle and adipose. Thus, cortisol acts as an antagonist of insulin action, and 11beta-HSD1 mediated production of cortisol has been hypothesized to contribute to human insulin resistance and type 2 diabetes.

Current treatments for type 2 diabetes typically address individual components of the disease, and few therapies target the multiple risk factors that lead to the elevated cardiovascular risk associated with this condition. By selectively inhibiting 11beta-HSD1 and reducing the level of cortisol in key metabolic tissues, INCB13739 has the potential to provide a broad spectrum impact on the multiple components seen in patients with type 2 diabetes.

About Type 2 Diabetes

According to the Centers for Disease Control and Prevention (CDC), nearly 21 million Americans have diabetes. The majority of these patients have type 2 diabetes. The CDC also reports that 41 million people are estimated to have pre-diabetes, a pre-disposing condition that occurs before the onset of type 2 diabetes.

About Incyte

Incyte Corporation is a Wilmington, Delaware-based drug discovery and development company with a growing pipeline of oral compounds to treat oncology, inflammation, HIV and diabetes.

Forward-Looking Statements

Except for the historical information contained herein, the matters set forth in this press release, including the expected utility of Incyte's 11beta-HSD1 inhibitor, INCB13739, and the expected plans and timing for Phase I and Phase IIa trials for INCB13739, 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 results of further research and development, the risk that results of clinical trials may be unsuccessful or insufficient to meet applicable development and regulatory standards, the high degree of risk associated with drug development, the ability of Incyte to compete against parties with greater financial or other resources and other risks detailed from time to time in Incyte's reports filed with the Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the quarter ended March 31, 2006. Incyte disclaims any intent or obligation to update these forward-looking statements.

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SOURCE: Incyte Corporation