CytoDyn Inc. Announces First HIV Patient Dosing With PRO 140 in Phase 2b Clinical Trial for Treatment Substitution Protocol

VANCOUVER, Wash., May 14, 2014 (GLOBE NEWSWIRE) -- CytoDyn Inc. (OTCQB:CYDY), a biotechnology company focused on the development of new therapies for combating infection with immune deficiency viruses, announced today that the Company has dosed the first patients in its Phase 2b clinical trial with its lead product candidate, PRO140. This trial is a treatment substitution protocol for patients with Human Immunodeficiency Virus (HIV).

The primary objective for this Phase 2b trial is to assess the efficacy of PRO 140 monotherapy for the maintenance of viral suppression in HIV patients who are stable on combination antiretroviral therapy, known as HAART (highly active antiretroviral therapy), but need or wish to discontinue HAART therapy temporarily. This new therapeutic regimen will potentially allow HIV patients to take a 'drug holiday' from their HAART with weekly injections of PRO 140. If the study is successful, twice-a-month and once-a-month self-injection therapy will also be evaluated.

Nader Pourhassan, Ph.D., CytoDyn's President and Chief Executive Officer, stated, "PRO 140 has the potential to change the treatment paradigm for patients with HIV/AIDS. We are very encouraged based on results from previous clinical trials that this study will provide a new therapeutic alternative. The formal initiation of this clinical trial marks a major step forward in the advancement of our lead product candidate. For the first time, the Company is sponsoring this clinical trial itself. In the past six months, PRO 140 has obtained a green light from the FDA for two Phase 2b clinical trials which we expect to ultimately deliver treatment alternatives for patients and value for our shareholders."

About PRO 140

PRO 140 belongs to a new class of HIV/AIDS therapeutics -- viral-entry inhibitors -- that are intended to protect healthy cells from viral infection. PRO 140 is a humanized monoclonal antibody directed against CCR5, a molecular portal that HIV uses to enter cells.

PRO 140 has been the subject of four Phase 1/1b and two Phase 2a clinical trials, each of which demonstrated its ability to significantly reduce HIV viral load in human test subjects, and has also been designated a "fast track" product candidate by the FDA. The PRO 140 antibody appears to be a powerful antiviral agent leading to potentially fewer side effects and less frequent dosing requirements as compared to daily drug therapies currently in use.
About CytoDyn

CytoDyn is a biotechnology company focused on developing subcutaneously delivered humanized cell-specific monoclonal antibodies (mAbs) as entry inhibitors for the treatment and prevention of Human Immunodeficiency Virus (HIV). The Company has one of the leading mAbs under development for HIV infection, PRO 140, which is a Late Stage 2 humanized mAb with demonstrated antiviral activity in man. PRO 140 blocks the HIV co-receptor CCR5 and clinical trial results thus far indicate that it does not affect the normal function of the cell. Results from Phase 1/1b and Phase 2a human clinical trials have shown that PRO 140 can significantly reduce viral burden in people infected with HIV. CytoDyn intends to continue to develop PRO 140 as a therapeutic anti-viral agent in persons infected with HIV. For more information on the Company please visit www.cytodyn.com.

Forward-Looking Statements

This press release includes forward-looking statements and forward-looking information within the meaning of United States securities laws. These statements and information represent CytoDyn's intentions, plans, expectations, and beliefs and are subject to risks, uncertainties and other factors, many beyond CytoDyn's control. These factors could cause actual results to differ materially from such forward-looking statements or information. The words "believe," "estimate," "expect," "intend," "attempt," "anticipate," "foresee," "plan," and similar expressions and variations thereof identify certain of such forward-looking statements or forward-looking information, which speak only as of the date on which they are made.

CytoDyn disclaims any intention or obligation to publicly update or revise any forward-looking statements or forward-looking information, whether as a result of new information, future events or otherwise, except as required by applicable law. Readers are cautioned not to place undue reliance on these forward-looking statements or forward-looking information. While it is impossible to identify or predict all such matters, these differences may result from, among other things, the inherent uncertainty of the timing and success of and expense associated with research, development, regulatory approval, and commercialization of CytoDyn's products and product candidates, including the risks that clinical trials will not commence or proceed as planned; products appearing promising in early trials will not demonstrate efficacy or safety in larger-scale trials; future clinical trial data on CytoDyn's products and product candidates will be unfavorable; funding for additional clinical trials may not be available; CytoDyn’s products may not receive marketing approval from regulators or, if approved, may fail to gain sufficient market acceptance to justify development and commercialization costs; competing products currently on the market or in development may reduce the commercial potential of CytoDyn's products; CytoDyn, its collaborators or others may identify side effects after the product is on the market; or efficacy or safety concerns regarding marketed products, whether or not scientifically justified, may lead to product recalls, withdrawals of marketing approval, reformulation of the product, additional pre-clinical testing or clinical trials, changes in labeling of the product, the need for additional marketing applications, or other adverse events.
CytoDyn is also subject to additional risks and uncertainties, including risks associated with the actions of its corporate, academic, and other collaborators and government regulatory agencies; risks from market forces and trends; potential product liability; intellectual property litigation; environmental and other risks; and risks that current and pending patent protection for its products may be invalid, unenforceable, or challenged or fail to provide adequate market exclusivity. There are also substantial risks arising out of CytoDyn's need to raise additional capital to develop its products and satisfy its financial obligations; the highly regulated nature of its business, including government cost-containment initiatives and restrictions on third-party payments for its products; the highly competitive nature of its industry; and other factors set forth in CytoDyn's Quarterly Report on Form 10-Q for the quarter ended February 28, 2014 and other reports filed with the U.S. Securities and Exchange Commission.

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