CytoDyn Submits Protocol for Phase 2b Trial for Treatment Naïve HIV Patients

This two-week study carries possibilities of breakthrough designation and orphan drug designation

VANCOUVER, Washington, July 19, 2016 (GLOBE NEWSWIRE) -- CytoDyn Inc. (OTCQB:CYDY), a biotechnology company focused on the development of new antibody therapies for combating human immunodeficiency virus (HIV) infection, announces that it has submitted a new protocol to the FDA for treatment naïve patients under its current open IND (Investigative New Drug application). This is a two-week Phase 2b, randomized, double-blind, placebo-controlled, multi-center study to assess safety and efficacy of PRO 140 (Monoclonal CCR5 antibody) in treatment-naïve adults with HIV-1 infection.

Treatment naïve patients are newly diagnosed with HIV and have not yet been prescribed with an antiretroviral therapy (“ART”) and are highly contagious until their ART is defined, prescribed and initiated. This period of time is also very dangerous for the patient as they may build resistance to the current approved classes of drug, thus limiting their available options to medication.

This 60-patient study is designed to evaluate the safety and efficacy of PRO 140 for two weeks administered subcutaneously compared to placebo for the reduction of viral load in treatment-naïve adult patients with HIV-1 infection before their first ART regimen is initiated. All eligible and consenting participants will be randomized in a 1:1 ratio to one of two treatment arms:

• Group A: PRO 140 350mg weekly subcutaneous injection
• Group B: Placebo weekly subcutaneous injection

Under the Company’s protocol, upon randomization, the 60 subjects will receive two doses of PRO 140 or placebo given seven days apart. The first dose of PRO 140 or placebo will be given on the day of randomization followed by second dose (one week later) at the initiation of HAART. Study participants will be monitored for one year following initiation of HAART.

The Company believes this proposed therapy represents the first time patients have had any therapeutic coverage in these initial two highly contagious weeks prior to initiation of an ART. The predominance of the R5 strain of HIV for newly diagnosed patients is approximately 85% to 90%. The approximate remaining 10% to 15% are primarily the Dual Mix strain of HIV, for which the Company believes PRO 140 may be effective for at least four weeks. In view of the two-week duration of this study, the Company believes PRO 140 will have application to approximately 99% of this population (R5 and Dual Mix combined) for the purpose of this study.

Nader Pourhassan, Ph.D., CytoDyn President and CEO, commented: “We believe our
treatment naïve trial for newly diagnosed patients may be an important therapeutic tool for containing viral transmission while patients await their ART.”

“With the addition of yet another new clinical indication, we believe now more than ever that PRO 140 has the potential to change the HIV-treatment paradigm,” noted Dr. Pourhassan. “PRO 140, as a combination to current drugs, could allow HIV patients to replace their most troubling portion of their HAART regimen. Moreover, we believe that PRO 140, as a monotherapy (single-agent maintenance therapy), could allow HIV patients that are exclusively infected with the R5 strain to replace their entire oral regimen with one weekly dose of PRO 140 through subcutaneous injection. Lastly, this new 60-patient two-week trial could present another opportunity to quickly advance PRO 140.”

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 IgG4 monoclonal antibody directed against CCR5, a molecular portal that HIV uses to enter T-cells. PRO 140 blocks the predominant HIV (R5) subtype entry into T-cells by masking this required co-receptor, CCR5. Importantly, PRO 140 does not appear to interfere with the normal function of CCR5 in mediating immune responses. PRO 140 does not have agonist activity toward CCR5 but does have antagonist activity to CCL5, which is a central mediator in inflammatory diseases. PRO 140 has been the subject of seven clinical trials, each demonstrating efficacy by significantly reducing or controlling HIV viral load in human test subjects. PRO 140 has 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 the clinical development and potential commercialization of humanized monoclonal antibodies for the treatment and prevention of HIV infection. The Company has one of the leading monoclonal antibodies under development for HIV infection, PRO 140, which has completed Phase 2 clinical trials with demonstrated antiviral activity in man and is currently in Phase 3. PRO 140 blocks the HIV co-receptor CCR5 on T cells, which prevents viral entry. Clinical trial results thus far indicate that PRO 140 does not negatively affect the normal immune functions that are mediated by CCR5. Results from seven Phase 1 and Phase 2 human clinical trials have shown that PRO 140 can significantly reduce viral burden in people infected with HIV. A recent Phase 2b clinical trial demonstrated that PRO 140 can prevent viral escape in patients during several weeks of interruption from conventional drug therapy. CytoDyn intends to continue to develop PRO 140 as a therapeutic anti-viral agent in persons infected with HIV and to pursue non-HIV indications where CCR5 and its ligand CCL5 may be involved. 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, including statements regarding CytoDyn’s protocol for treatment naïve patients and its proposed trial and other current and proposed trials and studies and their results and completion. 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 Annual Report on Form 10-K for the fiscal year ended May 31, 2015 and other reports filed with the U.S. Securities and Exchange Commission.

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