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Patients Approach Two Years of Complete HIV Viral Load Suppression in Phase 2b PRO 140 Monotherapy Extension Study

VANCOUVER, Washington, Aug. 23, 2016 (GLOBE NEWSWIRE) -- CytoDyn Inc. (OTC.QB:CYDY), a biotechnology company focused on the development of new antibody therapies for combating human immunodeficiency virus (HIV) infection, announces that the first of 11 HIV-1 patients receiving PRO 140 as a monotherapy in a Phase 2b extension study has reached two years of complete virologic suppression. Four additional patients are expected to reach the two-year benchmark in the next three weeks and five more patients are expected to reach this benchmark in approximately two months.

“We are pleased that 10 HIV patients who participated in our Phase 2b study are approaching the significant milestone of two years of complete virologic suppression on PRO 140 as a single agent,” said Nader Pourhassan, PhD, CytoDyn’s President and CEO. “These patients are receiving weekly subcutaneous PRO 140 injections as a substitution for daily regiments of Highly Active Antiretroviral Therapy (HAART) regimens without the notable drawbacks of HAART.”

Patients in the Phase 2b extension study showed full HIV viral load suppression during a 12-week Phase 2b study in which they receive weekly PRO 140 subcutaneous injections (one 350 mg dose) in place of their HAART regimens. Forty patients were enrolled in the Phase 2b trial, of which 35 were evaluable and five were excluded for tropism screening failures or protocol violations. Twenty patients completed the 12-week Phase 2b study with HIV viral load suppression and were eligible for the extension arm. Fifteen patients of the 20 were granted entry into the extension arm. Four of the fifteen patients that entered the extension arm were disqualified due to lack of follow-up (relocation) or disqualification unrelated to PRO 140 and one was a treatment failure, leaving 10 evaluable patients, which are now at or close to the two-year benchmark of complete HIV viral load suppression while on PRO 140 as a monotherapy.

Of the 11 patients currently receiving weekly PRO 140 injections in the Phase 2b extension study, one patient recently entered the study, having shown complete HIV viral load suppression following an initial 12-week treatment period. This patient was one of three patients who were allowed to qualify for the Phase 2b extension study within the past two to four months by the trial’s Data Safety Monitoring Board due to the disqualification of three patients in the original Phase 2b study for tropism screening errors.

Patients qualifying for the Phase 2b monotherapy study were evaluated for infection with strains of HIV-1 that utilize the CCR5 co-receptor. The PRO 140 monoclonal antibody targets CCR5 with high affinity and potently blocks HIV-1 cell entry. Complete virologic suppression is defined as plasma HIV-1 RNA less than 40 copies/mL, which is the lower limit

of detection in the commercial assay. Blood drawn after one year of monotherapy from nine patients in the Phase 2b extension study were tested with a single copy HIV-1 research test. In six of the nine patients whose viral load was checked with a single copy assay, the viral load was documented to be less than one HIV-1 RNA copy/mL blood and two patients had less than 4 copies/mL.

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 months 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 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, 2016 and other reports filed with the U.S. Securities and Exchange Commission.

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