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CytoDyn ASM Poster Presentation June 9, 2018, at ASM Microbe 2018, Atlanta, GA

VANCOUVER, Washington, June 11, 2018 (GLOBE NEWSWIRE) -- Results from a pivotal trial with PRO 140, a novel humanized CCR5 monoclonal antibody under development by CytoDyn Inc. (OTC.QB:CYDY), support the value of its use in combination with antiretroviral treatment (ART) as a long-acting therapeutic for heavily treatment-experienced HIV-1 infected patients. Results from the one-week, single-dose, randomized, double-blind, placebo-controlled portion of the pivotal trial showing that PRO 140 met the primary efficacy endpoint were presented on June 9 in a Late-Breaker Abstract poster session at the ASM Microbe 2018 meeting in Atlanta.

“While ART has greatly advanced over the years, new agents are needed to improve the potency and pharmacokinetic profiles, decrease toxicity, combat drug resistance, and improve convenience to facilitate patient compliance,” said Nader Pourhassan, Ph.D., CytoDyn’s President and Chief Executive Officer. “These trial results support the continued development of PRO 140 as a simple-to-administer, long-acting HIV-1 therapy that combined with ART can provide a valuable new therapeutic option for patients who have become resistant to two or more antiretroviral agents.”

Fifty patients, with demonstrated evidence of HIV-1 replication on existing ART and documented resistance to two or more antiretroviral drug classes, participated in the ongoing two-part pivotal trial. In the first one-week portion of the trial, patients were randomized into two arms with both arms continuing on existing ART and one arm administered a single PRO 140 350mg subcutaneous injection and the second arm receiving placebo. The trial met the primary efficacy endpoint: the proportion of patients with ≥0.5 $\log_{10}$ reduction in HIV-1 RNA viral load from baseline at the end of the one-week treatment period ($p<0.01$).

In part two of the trial, all patients receive 24 weeks of PRO 140 subcutaneous injections with optimized background ART in an open-label setting. Continuing access to PRO 140 is provided to patients completing 25 weeks in the trial.

“With the highly favorable efficacy results for our combination therapy trial, and data from our previous trials and our ongoing monotherapy trial, we are working toward the filing of a Biological License Application, or BLA, with the FDA for PRO 140 in the combination therapy setting,” said Dr. Pourhassan.

About PRO 140
PRO 140 belongs to a new class of HIV/AIDS therapeutics – viral-entry inhibitors – that is 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 by the FDA. The FDA also granted orphan drug designation to PRO 140 for the prevention of graft-versus-host disease (GvHD). The PRO 140 antibody appears to be a powerful antiviral agent leading to potentially fewer side effects and less frequent dosing requirements compared with 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 humans and is currently in Phase 3 development. 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, inflammatory indications where CCR5 and its ligand CCL5 may be involved. For more information on the Company, please visit http://www.cytodyn.com.

Forward-Looking Statements

This press release contains certain forward-looking statements that involve risks, uncertainties and assumptions that are difficult to predict, including statements regarding our current and proposed trials and studies and their enrollment, results, costs and completion. Words and expressions reflecting optimism, satisfaction or disappointment with current prospects, as well as words such as “believes,” “hopes,” “intends,” “estimates,” “expects,” “projects,” “plans,” “anticipates” and variations thereof, or the use of future tense, identify forward-looking statements, but their absence does not mean that a statement is not forward-looking. Our forward-looking statements are not guarantees of performance and actual results could differ materially from those contained in or expressed by such statements. In evaluating all such statements, we urge you to specifically consider the various risk factors identified in our Form 10-K for the fiscal year ended May 31, 2017 in the section titled “Risk Factors” in Part I, Item 1A and in our Form 10-Q for the quarterly period ended February 28, 2018 in the section titled “Risk Factors” in Part II, Item 1A, any of which could cause actual results to differ materially from those indicated by our forward-looking statements.

Our forward-looking statements reflect our current views with respect to future events and are based on currently available financial, economic, scientific, and competitive data and information on current business plans. You should not place undue reliance on our forward-looking statements, which are subject to risks and uncertainties relating to, among other things: (i) the sufficiency of our cash position and our ongoing ability to raise additional capital to fund our operations, (ii) our ability to complete our Phase 2b/3 pivotal combination

therapy trial for PRO 140 (CD02) and to meet the FDA's requirements with respect to safety and efficacy to support the filing of a Biologics License Application, (iii) our ability to meet our debt obligations, if any, (iv) our ability to identify patients to enroll in our clinical trials in a timely fashion, (v) our ability to achieve approval of a marketable product, (vi) design, implementation and conduct of clinical trials, (vii) the results of our clinical trials, including the possibility of unfavorable clinical trial results, (viii) the market for, and marketability of, any product that is approved, (ix) the existence or development of vaccines, drugs, or other treatments for infection with the Human Immunodeficiency Virus that are viewed by medical professionals or patients as superior to our products, (x) regulatory initiatives, compliance with governmental regulations and the regulatory approval process, (xi) general economic and business conditions, (xii) changes in foreign, political, and social conditions, and (xiii) various other matters, many of which are beyond our control. Should one or more of these risks or uncertainties develop, or should underlying assumptions prove to be incorrect, actual results may vary materially and adversely from those anticipated, believed, estimated, or otherwise indicated by our forward-looking statements.

We intend that all forward-looking statements made in this press release will be subject to the safe harbor protection of the federal securities laws pursuant to Section 27A of the Securities Act, to the extent applicable. Except as required by law, we do not undertake any responsibility to update these forward-looking statements to take into account events or circumstances that occur after the date of this press release. Additionally, we do not undertake any responsibility to update you on the occurrence of any unanticipated events which may cause actual results to differ from those expressed or implied by these forward-looking statements.

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