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CytoDyn to Present Primary Efficacy Endpoint Results from its PRO 140 Pivotal Trial in Late-Breaking Session at ASM Microbe 2018

VANCOUVER, Washington, April 11, 2018 (GLOBE NEWSWIRE) -- CytoDyn Inc. (OTC.QB:CYDY), a biotechnology company developing new antibody therapies for combating human immunodeficiency virus (HIV) infection, announces that an abstract with primary efficacy results from its PRO 140 pivotal combination therapy trial in treatment-experienced HIV patients has been accepted for presentation at a late-breaking session at ASM Microbe 2018. The conference is being held June 7-11, 2018 at the Georgia World Congress Center in Atlanta.

“The achievement of our primary efficacy endpoint in our pivotal combination therapy trial is a major inflection point for CytoDyn in advancing PRO 140 through the regulatory process and we are delighted to present these results in a late-breaking session at this year’s ASM Microbe Conference,” said Nader Pourhassan, Ph.D., CytoDyn President and Chief Executive Officer. “As previously announced, PRO 140 showed a statistically significant reduction in HIV-1 RNA viral load versus placebo in these antiretroviral treatment-experienced individuals who were failing their current HIV therapy.”

CytoDyn will highlight data from the abstract, “Primary Efficacy Results of PRO 140 SC in a Pivotal Phase 2b/3 Study in Heavily Treatment-Experienced HIV-1 Patients,” authored by K. Dhody, K. Kazempour, N. Pourhassan, P.J. Maddon, following the ASM Microbe 2018 presentation. The abstract is expected to be available online at the ASM Microbe 2018 website following conference conclusion. CytoDyn will also make the abstract available on its website at that time.

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 eight 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.

ASM Microbe 2018
The American Society for Microbiology (ASM) is the largest single life science society, composed of over 47,000 scientists and health professionals. ASM's mission is to promote and advance the microbial sciences. ASM Microbe 2018 connects scientists with their science, showcases the best microbial sciences in the world, and provides a one-of-a-kind forum to explore the complete spectrum of microbiology from basic science to translation and application.

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 eight 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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