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CytoDyn's Two-Year Update on Its PRO 140 Monotherapy Study in HIV Accepted at CROI 2017

VANCOUVER, Washington, Nov. 16, 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 an abstract featuring results from its ongoing Phase 2b extension study with PRO 140 as a monotherapy for the treatment of patients with HIV has been accepted for a poster presentation, as well as a "themed discussion" at the Conference on Retroviruses and Opportunistic Infections (CROI), which is being held in Seattle from February 13 to 16, 2017.

The abstract, "PRO 140 Single-Agent Maintenance Therapy for HIV-1 Infection: A 2-Year Update," was selected for a Themed Discussion Presentation by the CROI Program Committee. This presentation will include four or five abstracts merged into a special theme-oriented, hour-long discussion featuring a brief summary of noteworthy results, conclusions and discussion points. The presentations will be followed by an interactive discussion that synthesizes the relevant information of the abstracts, covers key points of agreement and controversy and draws comparisons to related work in the scientific field.

The abstract will provide an update on 10 patients with HIV who have successfully achieved complete viral load suppression for more than two years with PRO 140 administered in weekly subcutaneous injections. 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 for HIV detection and is the level at which HIV transmission is reduced by more than 96%.

"The results from this ongoing extension study are highly significant as PRO 140 is being substituted for the current standard of care Highly Active Antiretroviral Therapy (HAART)," said Nader Pourhassan, Ph.D., president and chief executive officer of CytoDyn. "Only about 30% of patients achieve lifelong viral load suppression on HAART, which also has notable drawbacks such as highly regimented daily dosing, toxicity and incomplete recovery of the immune system. All patients in the Phase 2b monotherapy study were evaluated for infection with strains of HIV-1 that utilize the CCR5 co-receptor as PRO 140 targets CCR5 with high affinity and potently blocks HIV-1 cell entry.

"We look forward to having results from our ongoing extension study presented to the many researchers and others involved in HIV/AIDS who will be attending CROI 2017," added Dr. Pourhassan. "We are advancing PRO 140 through the clinical development process both as a monotherapy and in combination with HAART. We anticipate announcing our primary efficacy endpoint results from the pivotal Phase 3 combination trial as early as the first quarter of 2017."

CROI Conference
The annual Conference on Retroviruses and Opportunistic Infections (CROI) brings together top basic, translational and clinical researchers from around the world to share the latest studies, important developments and best research methods in the ongoing battle against HIV/AIDS and related infectious diseases. CROI is a global model of collaborative science and the premier international venue for bridging basic and clinical investigation to clinical practice in the field of HIV and related viruses. Additional information about the conference is available at http://www.croiconference.org/.

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.

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.

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, costs 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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