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Data Presented at CROI Show CytoDyn’s Pro 140 as a Single Agent Provided Maximal Virologic Suppression in HIV Patients for Nearly Two Years

VANCOUVER, Washington, Feb. 15, 2017 (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 data from its ongoing Phase 2b extension study with PRO 140 administered as a single agent provided maximal virologic suppression and was well tolerated by 10 HIV-infected patients for nearly two years. The study data was the subject of a poster presentation by Dr. Kush Dhody, Senior Director, Clinical Operations at Amarex Clinical Research, at the Conference on Retroviruses and Opportunistic Infections (CROI) being held in Seattle.

The abstract and poster, entitled “PRO140 Single-Agent Maintenance Therapy for HIV-1 Infection: A 2-Year Update,” are available on the company’s website at www.cytodyn.com. The study data will also be featured at CROI 2017 in a special hour-long Themed Discussion, “I Want a New Drug,” on February 16 beginning at 1:30 p.m. Pacific time (4:30 p.m. Eastern time). A delayed webcast of the Themed Discussion will be available on February 17, 2017 by 2:30 p.m. Pacific time at croiwebcasts.org, then select “Feb 16” and scroll down to “I Want a New Drug.”

The poster reviews the two-year treatment data from the ongoing Phase 2b CD01 extension study into which 16 patients infected with CCR5-tropic HIV-1 were enrolled after maintaining virologic suppression (HIV-1 RNA levels below 40 copies/mL) following 12 weeks of weekly, subcutaneous injections of PRO 140 (350 mg) as a single agent under the initial CD01 study. Of the 16 patients, 14 were male and three were non-white; the median age was 54.9 years (range of 26-68) and median CD4 T-cell count was 593 cells/mm³ (range of 365-1059). These patients were trained to self-administer PRO 140 and were allowed to continue weekly subcutaneous injections as a monotherapy for up to three years (or 160 weeks). Of those enrolled, 13 patients (81.3%) maintained complete virologic suppression for more than 40 weeks and 10 patients (62.5%) maintained complete virologic suppression for nearly two years and are still continuing on PRO 140 monotherapy regimen. One patient discontinued at week 47 with complete virologic suppression due to relocation and five patients experienced virologic rebound, defined as two consecutive viral load measurements of ≥400 copies/mL. The mean time to virologic rebound was 329 days (range of 106-691). An advanced single-copy HIV RNA assay levels (to quantify the viral load below the limit of detection of commercially available assays) were evaluated for the 10 ongoing patients at two-year time point. Seven (7)
patients reported viral load of <1 copy/mL; and other 3 patients reported values of 4, 10, and 19 copies/mL. These single-copy HIV-1 RNA results provide further evidence of potent antiviral activity of PRO 140.

“HIV-infected patients are in need of new approaches for maintaining virologic suppression as many experience toxicity, intolerance or suboptimal adherence to the current standard of care, which is a daily oral combination antiretroviral therapy (ART),” said Dhody. “As highlighted in this poster, a subgroup of patients was able to maintain complete virologic suppression on PRO 140 over extended periods of time without the compliance, tolerance and resistance issues associated with oral combination ART. The strength of the data presented today demonstrates that PRO 140 warrants further evaluation as a long-acting, single-agent maintenance therapy in select HIV-1 patients. It is indeed an honor to present this data to attendees at CROI 2017.”

“PRO 140 is a humanized IgG4 monoclonal antibody that works by blocking HIV-1 from entering and infecting immune cells by binding to CCR5 with high affinity, which is a novel approach to maintaining virologic suppression,” said Paul J. Maddon, MD, PhD, inventor of PRO 140 and Senior Science Advisor to CytoDyn. “It is exciting that a group of patients self-administering PRO 140 as a monotherapy were able to avoid the potential toxicity of ART, while preserving their option to return to an ART regimen at a later date. PRO 140 was well tolerated by a majority of patients in this extension study and there were no reports of serious adverse events or treatment discontinuation related to the drug. As anticipated, no anti-PRO140 antibodies were detected in any patient, indicating there were no signs of drug resistance.”

**PRO 140 in Phase 3 Trials**

CytoDyn is evaluating PRO 140 in two Phase 3 trials in patients with CCR5-tropic HIV-1. The first is the multicenter, randomized, pivotal Phase 3 CD02 trial with PRO 140 in combination with other antiretroviral agents that is enrolling 30 treatment-experienced adult patients who have documented multi-antiretroviral class resistance and evidence of HIV-1 replication despite ongoing antiretroviral therapy. Enrolled patients continue their failing HAART regimen for one week for the efficacy portion of the trial. At the start of that week half of the patients are treated with PRO 140 and half are injected with a placebo. For PRO 140 to reach the primary efficacy endpoint, 90% of those injected with PRO 140 and less than 35% of those injected with placebo need to achieve 0.5 log reduction, or a three-fold decrease, in HIV-1 RNA levels versus baseline. Following the initial efficacy portion of the trial, patients are placed on optimized HAART along with weekly PRO 140 injections for a 24-week period to complete the safety portion of the trial.

Enrollment is also underway in the Phase 3 CD03 trial with PRO 140 as a single-agent maintenance therapy in virally suppressed subjects with HIV. This multicenter, open-label trial will enroll 300 patients with the objective of assessing the efficacy, safety and tolerability of PRO 140 as a long-acting, single-agent maintenance therapy for the chronic suppression of HIV. Patients enrolled in the trial will be shifted from daily ART regimens to weekly PRO 140 subcutaneous injections for 48 weeks.

“We are excited about both Phase 3 trials with PRO 140,” said Nader Pourhassan, PhD, President and Chief Executive Officer of CytoDyn. “While we believe PRO 140 as a
combination therapy offers the compelling advantage of allowing patients to discontinue the most toxic drug in their ART regimen, the results presented today provide sufficient reason to continue pursuing PRO 140 as a single-agent therapy. We are using our ongoing trials to evaluate a number of factors such as patient characteristics and dose levels that may predict PRO 140 treatment success in future studies.

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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