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CytoDyn Files for Breakthrough Therapy Designation With the FDA for PRO 140 in HIV Therapy

VANCOUVER, Washington, Jan. 11, 2017 (GLOBE NEWSWIRE) -- **CytoDyn Inc.** (OTC.QB:CYDY), a biotechnology company focused on the development of new therapies for combating human immunodeficiency virus (HIV) infection, today announced the Company filed a request for Breakthrough Therapy Designation with the FDA for PRO 140 as a treatment for HIV-1 infection in treatment-experienced patients with virologic failure.

While the standard of care for HIV infection has been a combination of medications from different antiretroviral classes that interfere with different steps of the HIV lifecycle, there is now a significant number of long-term survivors who are facing issues of drug resistance and need new treatment options. The Company believes this request for Breakthrough Therapy Designation addresses this unmet need for novel therapies for the growing number of heavily treatment-experienced HIV patients.

Based on results from four completed and ongoing clinical trials, the Company believes the PRO 140 treatment option addresses the unmet medical need for therapy options for HIV-1 infected patients with uncontrolled viral load, despite conventional Antiretroviral Therapy (ART).

Dr. Nader Pourhassan, CytoDyn's President and CEO, commented: "Investigators from several sites have requested continued access to PRO 140 to allow patients to continue deriving clinical benefit and maintain HIV-1 viral suppression after the end of treatment in the CD02 Phase 3 Combination Therapy study. Seven patients have entered the rollover study to receive continued access to PRO 140 after the completion of the 25-week treatment period in this study. Additionally, 10 patients in the ongoing Phase 2b extension arm of Monotherapy trial have shown suppressed viral load for two years. We believe PRO 140 has demonstrated its value as a combination therapy and as a single agent in patients with the R5 strain of HIV and are hopeful that receiving Breakthrough Therapy Designation will speed our BLA process to get this product to the market."

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.

CONTACTS:

Investors:

LHA

Jody Cain

Office: 310-691-7100

E-mail: jcain@lhai.com

Media:

Nader Pourhassan, Ph.D.

President & CEO

Office: 360-980-8524

Email: npourhassan@cytodyn.com



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