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

VANCOUVER, Wash., Jan. 22, 2016 (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 the combination of medications from different antiretroviral (ART) classes that interfere with different steps of the viral lifecycle, there is now a significant number of long-term survivors who are facing issues of drug resistance and are in need of new treatment options (Pennings 2013, Cossarini et al. 2013). The Company believes this request for Breakthrough Therapy Designation addresses the unmet need for novel therapies for the growing number of heavily treatment-experienced HIV patients, who face a dwindling pool of effective therapeutic options in the face of uncontrolled viral load and low CD4+ T-cell counts.

Three clinical trials form the basis for this Breakthrough Therapy Designation request:

Study 1: Clinical study “PRO 140 2101” was a Phase 2a, randomized, double-blind, placebo-controlled study of PRO 140 by subcutaneous administration in adult subjects with HIV Type-1 infection. These patients had viral loads detectable at about 10,000 copies per mL on average.

Study 2: PRO 140_CD01 trial was designed to evaluate the efficacy, safety, and tolerability of PRO 140 monotherapy for the maintenance of viral suppression in patients who were stable on combination ART therapy in 40 subjects. Subjects were shifted from daily ART regimen to PRO 140 monotherapy for up to 12 weeks. Those subjects who were able to maintain viral suppression were allowed to continue PRO 140 monotherapy for an additional 60 weeks under the extension study.

Study 3: Subjects who completed the first 12 weeks of PRO 140 monotherapy in the PRO 140_CD 01 substitution study were provided an opportunity to participate in the extension study. A total of 15 subjects participated in the PRO 140_CD 01-extension study, of which 11 subjects are currently ongoing, and have completed more than one year (56-67 weeks) on PRO 140 monotherapy.

Altogether, the three clinical studies demonstrate the proof of concept that PRO 140 monotherapy can reduce the viral load in HIV-1 infected, treatment-experienced patients. Once the viral load is undetectable, weekly administration of PRO 140 can help maintain the

lower viral load in about 50% of patients over an extended period of time (currently shown to be over one year). Based on these preliminary results, the Company believes this treatment option addresses the unmet medical need for therapy options for HIV-1 infected patients with uncontrolled viral load, despite conventional ART. The patients who do not benefit from continuing ART could potentially benefit from PRO 140 therapy.

Dr. Nader Pourhassan, CytoDyn's President and CEO, commented: "Our monotherapy trial and its extension arm, along with prior studies of PRO 140 in HIV patients with detectable and none detectable viral load demonstrates that PRO 140 can reduce the viral load by as much as 1.6 log in three weeks. Once the viral load is undetectable, PRO 140 can keep the viral load suppressed, as evidenced in our ongoing extension study. We believe that if this Breakthrough Therapy Designation request is accepted, it will accelerate the process of bringing PRO 140 as a treatment option for patients who have no other alternatives."

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 Human Immunodeficiency Virus (HIV) infection. The Company has one of the leading monoclonal antibodies under development for HIV infection, PRO 140, which has finished 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 six 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 weeks 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 fully 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 towards 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 the Company's Phase 3 and other current and proposed studies and their results 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, 2015 and other reports filed with the U.S. Securities and Exchange Commission.

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