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# CytoDyn Files Protocol for Extended Access to PRO 140 for Patients Who Reach the End of PRO 140 Pivotal Phase 3 Trial

VANCOUVER, Washington, Oct. 24, 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, announced today that it filed a new roll-over protocol allowing all ongoing patients who reach the end of the Phase 3 combination study to continue receiving PRO 140.

The primary intent of this roll-over protocol is to provide PRO 140 for a second patient, who has completed this study, and all other future patients who complete participation in the Phase 3 combination study and would require continued access to PRO 140 to form a viable regimen, in the judgment of the treating physician.

CytoDyn submitted, and received, a single-subject compassionate use protocol when the first patient completed the Phase 3 combination study and the treating physician requested continued access to PRO 140 in order for the patient to continue deriving clinical benefit and to maintain HIV-1 viral suppression.

The Company expects that other clinical sites will have the same request, as the patients enrolled in the Phase 3 combination study are heavily treatment experienced and may require continued access to PRO 140 to maintain viral suppression. Therefore, CytoDyn decided to submit a new roll-over protocol that would allow all ongoing and future patients who successfully complete one week of efficacy followed by 24 weeks of safety treatment with PRO 140 under the Phase 3 combination study to receive continued access to PRO 140.

CytoDyn recently announced that following a meeting with the U.S. Food and Drug Administration, the Company reduced the number of patients required for its Phase trial to thirty (30) patients. In addition, the primary endpoint was reduced to a viral load drop of 3 fold (0.5log) from a drop of 5 fold (0.7log). Furthermore, data from CytoDyn's second monotherapy trial (with first patient dosing expected in 2016) will be used for the safety portion of the Phase 3 combination therapy trial.

Dr. Nader Pourhassan, President and CEO, commented: "Investigators in the ongoing Phase 3 combination trial have expressed a medical need for enrolled patients to remain on PRO 140 in order to maintain a suppressed viral load." Dr. Pourhassan added: "We are pleased that our primary endpoint results for this pivotal Phase 3 trial could be achieved by the first quarter of 2017. In addition, we are encouraged by the lowering of the primary

endpoint to a viral load reduction of 3 fold after one week, which compares favorably to the 10 fold to 20 fold viral load drop demonstrated by PRO 140 in three previous clinical trials with the same or less dose of PRO 140 in one week."

**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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