July 30, 2018

CytoDyn Announces Significantly Improved Response Rate at Higher Dose of PRO 140 in HIV Phase 3 Monotherapy Trial

- **Response rate increases from 40% at 350 mg dose to approximately 70% at 525 mg**
- **IRB approves monotherapy protocol modified to include 700 mg dose**
- **PRO 140 monotherapy, if approved, will allow patients to self-administer once per week at home without need for daily pills**

VANCOUVER, Washington, July 30, 2018 (GLOBE NEWSWIRE) -- CytoDyn Inc. (OTC.QB: CYDY), a biotechnology company developing a novel humanized CCR5 monoclonal antibody for multiple therapeutic indications, announces clearance from the independent Institutional Review Board (IRB) overseeing its CD03 Phase 3 investigative monotherapy trial to increase the weekly PRO 140 dose from 525 mg to 700 mg for newly enrolled patients. Current participants in the trial who failed to maintain suppressed HIV viral load on a lower dose of PRO 140 will be permitted to continue in the trial with a higher dose. The objective of this trial is to assess the efficacy, safety and tolerability of PRO 140 as a long-acting, single-agent maintenance therapy for the chronic suppression of HIV.

“This IRB decision is exciting for patients, our Company and our shareholders, given the potential for a higher patient response rate with PRO 140 as a single agent at the 700 mg dose level,” said Nader Pourhassan, Ph.D., CytoDyn’s president and chief executive officer. “Approximately 70% of trial participants who started with PRO 140 at the 525 mg dose and have been treated between one and nine months are achieving HIV viral load suppression. This response rate is very promising and we are excited to evaluate PRO 140 at an even a higher dose.”

Dr. Pourhassan noted that the exact response rates for PRO 140 at 525 mg could vary as the trial progresses. To date, there has been a clear distinction between patient response rates with PRO 140 at the lower 350 mg and higher 525 mg doses. CytoDyn believes that dosing PRO 140 at the 700 mg dose has the potential to achieve an even higher response rate than the approximate 70% currently observed at the 525 mg dose.

“We are able to increase the dose of PRO 140 due to its positive safety profile in prior clinical trials,” Dr. Pourhassan commented. “That was among the important factors considered by the IRB in providing this clearance.”

Patients enrolled in the Phase 3 monotherapy trial were prescreened for CCR5-tropic HIV-1 infection and suppressed HIV viral load under an existing highly active antiretroviral therapy (HAART) regimen. CytoDyn initiated the trial treating patients with weekly PRO 140 at 350 mg and found that approximately 40% were able to maintain suppressed HIV viral load. Following treatment of the first 150 patients, the protocol was revised to increase the weekly dose of PRO 140 to 525 mg. Patients who were non-responders to PRO 140 at the 350 mg dose were given the opportunity to switch to the higher 525 mg dose, and a majority were able to re-suppress with the higher dose.

"We were pleased that more than 20 patients achieved re-suppressed HIV viral load on PRO 140 525 mg dose after failing the lower PRO 140 350 mg dose and were able to continue in the trial," said Dr. Pourhassan. "Also of note, patients who achieve suppressed HIV viral load after 10 weeks tend to maintain suppressed viral load. Interestingly, some patients in our Phase 2b extension study are now achieving suppressed HIV viral load for nearly four years with PRO 140 as a single agent."

"Of key importance in the Phase 3 monotherapy trial, all non-responders to PRO 140 have safely achieved suppressed HIV viral load upon returning to their prior HAART regimens before PRO 140 monotherapy," said Jacob Lalezari, M.D., Director of Quest Clinical Research, Assistant Clinical Professor of Medicine at UCSF/Mount Zion Hospital and principal investigator of CytoDyn's Phase 2 monotherapy trial. "This is a major achievement as patients continue to have options for maintaining HIV viral load suppression."

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 humans and is currently in Phase 3 development. 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, inflammatory indications where CCR5 and its ligand CCL5 may be involved. For more information on the Company, please visit http://www.cytodyn.com.

About PRO 140
PRO 140 is a humanized IgG4 monoclonal antibody that blocks CCR5, a cellular receptor that plays multiple roles with implications in HIV infection, tumor metastasis, and immune signaling.

In the setting of HIV/AIDS, PRO 140 belongs to a new class of therapeutics called viral-entry inhibitors; it masks CCR5, thus protecting healthy T cells from viral infection by

blocking the predominant HIV (R5) subtype from entering those cells. At the same time, PRO 140 does not appear to interfere with the normal function of CCR5 in mediating immune responses. 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 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 compared with daily drug therapies currently in use.

In the setting of cancer, research has shown that CCR5 plays a central role in tumor invasion and metastasis, and that an increased CCR5 is an indicator of disease status in several cancers. Moreover, researchers have shown that drugs that block CCR5, including PRO 140, can block tumor metastases in laboratory and animal models of aggressive breast and prostate cancer. CytoDyn is conducting additional research with PRO 140 in the cancer setting and plans to initiate Phase 2 human clinical trials when appropriate.

The CCR5 receptor also plays a central role in modulating immune cell trafficking to sites of inflammation, and it is crucial for the development of acute graft-versus-host disease (GvHD) and other inflammatory conditions. Clinical studies by others have shown that blocking CCR5 using a chemical
inhibitor can reduce the clinical impact of acute GvHD without significantly affecting the engraftment of transplanted bone marrow stem cells. CytoDyn is currently conducting a Phase 2 clinical study with PRO 140 to further support the concept that the CCR5 receptor on engrafted cells is critical for the development of acute GvHD, and that blocking this receptor from recognizing certain immune signaling molecules is a viable approach to mitigating acute GvHD. The FDA has granted orphan drug designation to PRO 140 for the prevention of graft-versus-host disease (GvHD).

Forward-Looking Statements
This press release contains certain forward-looking statements that involve risks, uncertainties and assumptions that are difficult to predict, including statements regarding the potential acquisition, the likelihood of closing the potential transaction, our current clinical focus, our current and proposed trials and studies and their enrollment, results, costs and completion. Words and expressions reflecting optimism, satisfaction or disappointment with current prospects, as well as words such as “believes,” “hopes,” “intends,” “estimates,” “expects,” “projects,” “plans,” “anticipates” and variations thereof, or the use of future tense, identify forward-looking statements, but their absence does not mean that a statement is not forward-looking. Our forward-looking statements are not guarantees of performance and actual results could differ materially from those contained in or expressed by such statements. In evaluating all such statements, we urge you to specifically consider the various risk factors identified in our Form 10-K for the fiscal year ended May 31, 2018 in the section titled “Risk Factors” in Part I, Item 1A, any of which could cause actual results to differ materially from those indicated by our forward-looking statements.

Our forward-looking statements reflect our current views with respect to future events and are based on currently available financial, economic, scientific, and competitive data and information on current business plans. You should not place undue reliance on our

forward-looking statements, which are subject to risks and uncertainties relating to, among other things: (i) the completion of due diligence review, customary definitive documentation, deal structure and requisite corporate and regulatory approvals relating to the proposed transaction with ProstaGene, (ii) the sufficiency of our cash position and our ongoing ability to raise additional capital to fund our operations, (iii) our ability to complete our Phase 2b/3 pivotal combination therapy trial for PRO 140 (CD02) and to meet the FDA's requirements with respect to safety and efficacy to support the filing of a Biologics License Application, (iv) our ability to meet our debt obligations, if any, (v) our ability to identify patients to enroll in our clinical trials in a timely fashion, (vi) our ability to achieve approval of a marketable product, (vii) design, implementation and conduct of clinical trials, (viii) the results of our clinical trials, including the possibility of unfavorable clinical trial results, (ix) the market for, and marketability of, any product that is approved, (x) the existence or development of vaccines, drugs, or other treatments for infection with the Human Immunodeficiency Virus that are viewed by medical professionals or patients as superior to our products, (xi) regulatory initiatives, compliance with governmental regulations and the regulatory approval process, (xii) general economic and business conditions, (xiii) changes in foreign, political, and social conditions, and (xiv) various other matters, many of which are beyond our control. Should one or more of these risks or uncertainties develop, or should underlying assumptions prove to be incorrect, actual results may vary materially and adversely from those anticipated, believed, estimated, or otherwise indicated by our forward-looking statements.

We intend that all forward-looking statements made in this press release will be subject to the safe harbor protection of the federal securities laws pursuant to Section 27A of the Securities Act, to the extent applicable. Except as required by law, we do not undertake any responsibility to update these forward-looking statements to take into account events or circumstances that occur after the date of this press release. Additionally, we do not undertake any responsibility to update you on the occurrence of any unanticipated events which may cause actual results to differ from those expressed or implied by these forward-looking statements.

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