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## Data from PRO 140 (Ieronlimab) HIV Monotherapy Trial Selected for Presentation at CROI 2019

VANCOUVER, Washington, Nov. 16, 2018 (GLOBE NEWSWIRE) -- CytoDyn Inc. (OTC.QB: CYDY), a biotechnology company developing a novel humanized CCR5 monoclonal antibody for multiple therapeutic indications, announces that data from its ongoing CD03 investigative trial with PRO 140 (Ieronlimab) as a single-agent subcutaneous (SC) therapy in HIV-1 infected patients has been accepted for a poster presentation at the 2019 Conference on Retroviruses and Opportunistic Infections (CROI). The abstract, "*PRO 140 SC: Long-acting, Single-agent Maintenance Therapy for HIV-1 Infection*," will be presented by Dr. Kush Dhody, Vice President, Clinical Operations at Amarex Clinical Research, at CROI 2019, which is being held March 4-7, 2019 in Seattle.

"We are highly encouraged by the recently reported data from our monotherapy trial for patients receiving once-weekly injections of PRO 140 700 mg," said Nader Pourhassan, Ph.D., CytoDyn President and CEO. "As previously announced, we plan to file a pivotal phase 3 protocol for PRO 140 as a monotherapy for HIV-infected patients before the end of this year. We are excited to share the most recent data from this important clinical trial at CROI, which each year attracts many of world's leading clinicians in HIV research."

"The option of achieving suppressed HIV viral load with a single-agent, subcutaneous, self-administered, once-weekly injections could be life altering for HIV-infected patients," added Paul J. Maddon, M.D., Ph.D., inventor of PRO 140, senior science advisor to CytoDyn, and senior author of the abstract.

A press release summarizing the presented data from the Phase 3 PRO 140 monotherapy trial will be issued following the poster presentation at CROI 2019. The abstract and poster will be available on the Company's website at [www.cytodyn.com](http://www.cytodyn.com) at approximately the same time as the poster presentation.

CytoDyn is on track to complete a biologics license application (BLA) with the FDA for PRO 140 as a combination therapy with HAART for HIV-infected patients by the first quarter of 2019. Subject to approval by the FDA as a combination therapy, CytoDyn plans to file for a label expansion for PRO 140 as a monotherapy, with the filing to include data from the proposed Phase 3 pivotal trial with PRO 140 as a monotherapy.

### CROI 2019

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 the preeminent HIV research meeting in

the world and attracts more than 4,000 HIV/AIDS research leaders internationally. The goal of the conference is to provide a forum for researchers to translate their laboratory and clinical findings into tangible progress against the HIV pandemic. CROI has facilitated the presentation of important discoveries in the field, thereby ultimately accelerating progress in HIV/AIDS research.

### **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 increased CCR5 expression is an indicator of disease status in several cancers. Moreover, researchers have shown that drugs that block CCR5 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).

### **About CytoDyn**

CytoDyn is a biotechnology company developing innovative treatments for multiple therapeutic indications based on PRO 140 (Ieronlimab), a novel humanized monoclonal antibody targeting the CCR5 receptor. CCR5 plays a key role in the ability of HIV to enter and infect healthy T-cells. The CCR5 receptor is also implicated in tumor metastasis and in immune-mediated illnesses such as graft-vs-host disease (GvHD) and NASH. CytoDyn has successfully completed a Phase 3 pivotal trial with PRO 140 in combination with standard anti-retroviral therapies in HIV-infected treatment-experienced patients. The Company plans to seek FDA approval for PRO 140 in combination therapy and plans to complete the filing of a Biological License Application (BLA) in the first quarter of 2019 for that indication. CytoDyn is also conducting a Phase 3 investigative trial with PRO 140 as a once-weekly monotherapy

for HIV-infected patients, and plans to initiate a registration-directed study of PRO 140 monotherapy indication, which if successful, could support a label extension. Clinical results to date from multiple trials have shown that PRO 140 can significantly reduce viral burden in people infected with HIV with no reported drug-related serious adverse events (SAEs). Moreover, results from a Phase 2b clinical trial demonstrated that PRO 140 monotherapy can prevent viral escape in HIV-infected patients, with some patients on PRO 140 monotherapy remaining virally suppressed for more than four years. CytoDyn is also conducting a Phase 2 trial to evaluate PRO 140 for the prevention of GvHD and expects to initiate clinical trials with PRO 140 in metastatic triple-negative breast cancer in 2018. More information is at [www.cytodyn.com](http://www.cytodyn.com).

### **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 preliminary data from its ongoing clinical trials, the Company's clinical focus, and the Company's current and proposed trials. 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. The Company's 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, the Company urges investors to specifically consider the various risk factors identified in the Company's Form 10-K for the fiscal year ended May 31, 2018 in the section titled "Risk Factors" in Part I, Item 1A, and in our Form 10-Q for the quarterly period ended August 31, 2018 in the section titled "Risk Factors" in Part II, Item 1A, any of which could cause actual results to differ materially from those indicated by the Company's forward-looking statements.

The Company's forward-looking statements reflect its 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. Investors should not place undue reliance on the Company's forward-looking statements, which are subject to risks and uncertainties relating to, among other things: (i) the sufficiency of the Company's cash position and the Company's ongoing ability to raise additional capital to fund its operations, (ii) the Company's ability to complete its 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, (iii) the Company's ability to meet its debt obligations, if any, (iv) the Company's ability to identify patients to enroll in its clinical trials in a timely fashion, (v) the Company's ability to achieve approval of a marketable product, (vi) design, implementation and conduct of clinical trials, (vii) the results of the Company's clinical trials, including the possibility of unfavorable clinical trial results, (viii) the market for, and marketability of, any product that is approved, (ix) the existence or development of vaccines, drugs, or other treatments for infection with HIV that are viewed by medical professionals or patients as superior to the Company's products, (x) regulatory initiatives, compliance with governmental regulations and the regulatory approval process, (xi) general economic and business conditions, (xii) changes in foreign, political, and social conditions, and (xiii) various other matters, many of which are beyond the Company's 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 the Company's forward-looking statements.

The Company intends 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 of 1933, as amended, to the extent applicable. Except as required by law, the Company does 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, the Company does not undertake any responsibility to update investors upon 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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Source: CytoDyn Inc.