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CytoDyn's PRO 140 (Ieronlimab) HIV Monotherapy Trial Results Show 92% Responder's Rate at 700 mg Dose

Pivotal protocol for PRO 140 monotherapy trial to be filed with FDA in 2018

Once-weekly simple subcutaneous injections replaces HAART for certain HIV-infected patients

Phase 3 PRO 140 HIV monotherapy results feature:

- Nearly **1 year** of viral load suppression with PRO 140 350 mg dose without HAART: **40 patients**
- Nearly **1 year** of viral load suppression with PRO 140 525 mg dose without HAART: **21 patients**
- Majority of viral load breakouts due to events (i.e., influenza) that cause rise in T-cells
- Responder's rate with 350 mg dose at approximately 44%
- Responder's rate with 525 mg dose at approximately 71%
- Responder's rate with 700 mg dose at approximately 92%

VANCOUVER, Washington, Nov. 13, 2018 (GLOBE NEWSWIRE) -- CytoDyn Inc. (OTC.QB: CYDY), a biotechnology company developing a novel humanized CCR5 monoclonal antibody for multiple therapeutic indications, provides an update on PRO 140 (Ieronlimab) as a single agent for maintenance of HIV viral load suppression (HIV-1 RNA < 40 copies/mL). To date, approximately 92% (or 24 out of 26) newly enrolled patients administered PRO 140 700 mg in the CD03 Phase 3 investigative monotherapy trial treated for up to 12 weeks have achieved viral load suppression. Patients enrolled in the Phase 3 monotherapy trial were prescreened for CCR5-tropic HIV-1 infection.

"Our analysis of data indicate that patients treated with PRO 140 700 mg dose who achieve suppressed viral load at the six-week mark are highly likely to continue to maintain suppressed viral load," said Nader Pourhassan, Ph.D., CytoDyn President and CEO. "Given these promising data (92% responder rate), we plan to submit a pivotal monotherapy trial protocol for PRO 140 as a single-agent maintenance therapy before the end of 2018 with the intention of filing for a label expansion subject to combination therapy's first approval," explained Pourhassan.

"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, and principal investigator of CytoDyn's Phase 2 and Phase 3 PRO 140 investigative monotherapy trial. "This is a major achievement as patients continue to have options for maintaining HIV viral load suppression."

"It appears most of the viral load breakouts in patients in the 700 mg dose arm are due to an event such as a flu or vaccination that cause the number of T-cells to rise. With additional T-cells, numerous additional CCR5 co-receptors must be covered by PRO 140 to maintain suppressed HIV viral load. Among the patients enrolled thus far in the 700 mg dose arm, only two viral load breakouts have been noted, one patient received a vaccination and the second patient's breakout is still being investigated," added Dr. Lalezari.

CytoDyn remains on track to complete its filing of a biologics license application (BLA) for PRO 140 as a combination therapy for HIV patients with the FDA by the first quarter of 2019. Based on a Company-commissioned research report by BioVid Corporation, the Company estimates the U.S. market opportunity for PRO 140 as a combination therapy for HIV at approximately \$1.2 billion annually. Furthermore, the BioVid report estimates that 40% of the market potential for PRO 140 as a combination therapy may be realized during the first year of commercialization, which could equate to \$480 million in revenues.

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.

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 potential market size and projected revenues, 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.