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CytoDyn Files IND and Protocol for Phase 1b/2 Clinical Trial in Metastatic Triple-Negative Breast Cancer with PRO 140 (Leronlimab)

VANCOUVER, Washington, Nov. 05, 2018 (GLOBE NEWSWIRE) -- CytoDyn Inc. (OTC.QB: CYDY), a biotechnology company developing a novel humanized CCR5 monoclonal antibody for multiple therapeutic indications, announces that it has submitted an investigational new drug (IND) application to the U.S. Food and Drug Administration (FDA) to conduct a Phase 1b/2 clinical trial with PRO 140 (leronlimab) as a therapy for patients with metastatic triple-negative breast cancer. Triple-negative breast cancer represents an aggressive type of breast cancer with limited therapeutic options due to lack of standard biomarkers for targeted options.

“The filing of an IND and protocol is a critical next step in aggressively pursuing the development of PRO 140 in patients with this subtype of breast cancer who have poor prognoses and few treatment options,” said Nader Pourhassan, Ph.D., CytoDyn’s President and Chief Executive Officer. “The FDA typically requires 30 days to review an IND and protocol submission. If we receive no comments within that time period, we can begin enrolling patients.”

“I’m delighted to announce that Dr. Massimo Cristofanilli, an internationally renowned medical oncologist and thought leader on treatment options for women with breast cancer, has agreed to serve as the trial’s principal investigator. He will lead the trial’s team of investigators, which will include distinguished oncologists at other academic cancer centers,” added Dr. Pourhassan. Dr. Cristofanilli is Professor of Medicine (Division of Hematology and Oncology), Robert H. Lurie Comprehensive Cancer Center of Northwestern University, Feinberg School of Medicine in Chicago.

“Our optimism about PRO 140 (leronlimab) as a therapy for women with metastatic triple-negative breast cancer is predicated on previously announced findings from preclinical studies showing the ability of PRO 140 to block human breast cancer cellular invasion in a surrogate assay for metastatic breast cancer,” explained Dr. Pourhassan.

The original research and issued patents on CCR5 as a therapeutic target for cancer treatment were conducted by Richard Pestell, M.D., Ph.D., CytoDyn’s Interim Chief Medical Officer. CCR5 inhibitors blocked the spread of highly metastatic human breast cancers in preclinical studies in animals. Dr. Pestell’s published findings demonstrated that CCR5 is a crucial receptor in the growth, invasion and metastasis of human cancers (1-3). The CCR5 antagonist PRO 140 has recently been shown to inhibit human breast

cancer cell invasion and colon cancer tumor growth.

“We are honored to have Dr. Pestell lead this effort by overseeing the advancement of PRO 140 in this indication and other planned oncology and autoimmune disease studies,” added Dr. Pourhassan.

"If the early analysis of the trial will demonstrate positive clinical activity, CytoDyn expects to file for breakthrough therapy designation. During the study, a number of correlative studies will be measured to better understand the mode of action of PRO 140, primarily circulating tumor cells (CTC). CTC promotes metastasis and metastasis is the leading cause of death of cancer patients. If PRO 140 decreases the CTC by blocking the CCR5 receptor, then we believe PRO 140 may have the potential to disrupt the current standard of care treatments in a variety of cancer indications," stated Dr. Pourhassan.

Dr. Pestell noted, “In my previous study of 2,200 patients showed that more than 50% of all breast cancer overexpress CCR5 and more than 90% of patients with triple-negative breast cancer re-expressed CCR5 selectively on their cancer. PRO 140, which has been shown as very safe without any reported drug-related serious adverse events in more than 620 patients, binds avidly to CCR5 on human breast cancers. Together these findings suggest PRO 140 may be both a highly selective and safe therapeutic for patients with metastatic breast cancer. The ability to demonstrate efficacy in this patient population could serve as proof-of-concept of PRO 140’s potential to have a positive effect in other types of metastatic cancers. We look forward to detailing the protocol for this trial following the FDA review period.”

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 (leronlimab), 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 the proposed transaction with ProstaGene, the closing conditions and the likelihood of closing the proposed transaction with ProstaGene, 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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CytoDyn

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