November 26, 2018

CytoDyn Announces Initiation of Metastatic Triple Negative Breast Cancer Trial and Reiterates Phase 3 Goal in Cancer

VANCOUVER, Washington, Nov. 26, 2018 (GLOBE NEWSWIRE) -- CytoDyn Inc. (OTCQB:CYDY), a biotechnology company developing a novel humanized CCR5 monoclonal antibody for multiple therapeutic indications, including metastatic cancers, human immunodeficiency virus (HIV) and graft-versus-host disease (GvHD) is pleased to announce that on November 23, 2018, it received FDA approval of its IND submission and is allowed to initiate a phase 1b/2 clinical trial for metastatic triple-negative breast cancer (TNBC) patients.

CytoDyn has identified five clinical trial sites and intends to dose its first several patients and expects to have initial readout during the first quarter of 2019. The change in circulating tumor cells (CTCs) number will be evaluated every 21 days during treatment and will be used as an initial prognostic marker for efficacy. Up to 48 patients are expected to be enrolled in this study.

The Company presented Dr. Pestell's research which showed three key properties of the CCR5's Mechanism of Action (MOA). The first is that the CCR5 receptor on cancer cells was responsible for the migration and invasion of cells into the blood stream, which leads to metastasis of breast, prostate, and colon cancer. The second is that blocking the CCR5 also turns on anti-tumor fighting properties restoring immune function. The third key finding was that blockage of the CCR5/CCL5 interaction had a synergistic effect with chemotherapeutic therapy and controlled cancer progression. Chemotherapy traditionally increased expression of CCR5 so blocking it is expected to reduce the levels of invasion and metastasis. These effects are documented on the Company's most recent investor presentation available at www.cytodyn.com.

Dr. Richard Pestell, M.D., Ph.D., F.A.C.P., M.B.A., CytoDyn's Chief Medical Officer, was previously the Director of two National Cancer Institute Cancer Centers that focused on innovation for novel cancer treatments and trials. Dr. Pestell noted, "Metastatic triple-negative breast cancer (TNBC) is a deadly disease with poor prognosis due to the spread of the cancer in the blood stream. This type of breast cancer affects younger people, African Americans, Hispanics, and/or those with a BRCA1 gene mutation. Current therapies are directed to the primary tumor, rather than the movement or spread of the cancer in the blood stream. Unfortunately, the survival rate for metastatic TNBC patients are about 9 to 13 months with standard chemotherapy. In order to really impact cancer

survival, we need to control the metastasis. We recently discovered that the receptor CCR5, which is required for the entry of HIV into immune cells, is also expressed on cancer cells. CCR5 on cancer cells promotes the cancer cell spread in the blood stream. CCR5 controls homing of metastasis to the bones, brain, lung and other sites. PRO 140 binds CCR5 in cancer cells, so we believe we can now directly target the metastatic process. Our previously published studies of 2,200 breast cancer patients showed that CCR5 is overexpressed on over 95% of TNBC patient tumors, making CCR5 an ideal target for this disease."

"In recent months, CCR5 as a cancer therapeutic target has become the focus of pharmaceutical clinical development with the activation of two prospective Phase 2 clinical trials using small molecular inhibitors of CCR5. In contrast with small molecule inhibitors of CCR5, we believe that the use of a monoclonal antibody such as PRO 140 can offer increased efficacy and a better safety profile," stated Dr. Massimo Cristofanilli, a leader in the breast oncology field, medical oncologist and the Principal Investigator of the CytoDyn clinical trial notes. "As it stands now, TNBC is still an unmet medical need because it remains highly metastatic and difficult to treat. Novel therapies have to focus on targeting the metastatic process to improve outcome of these patients. In this study, we will measure clinical and biological endpoints, in addition to progression free survival, we will monitor Circulating Tumor Cells (CTC)'s in the blood," added Dr. Massimo Cristofanilli. Noted Dr. Pestell, "The blood tests of CTCs will give us deep insight into what is happening on a *real time* basis and allow us to communicate our progress."

"The new energy in the Company from the acquisition of ProstaGene is very positive," said Nader Pourhassan, Ph.D., CytoDyn's President and Chief Executive Officer. "As we have previously disclosed, we intend to execute on our timeline for clinical trial development of TNBC. Our first milestone was to start the TNBC trial this year. We are pleased that we are ahead of schedule. We also intend to file for Breakthrough Therapy Designation (BTD) and orphan drug designation if interim results are positive. We are also very excited that we are moving from a two-indication company to a platform technology company with potentially six indications and a prognostic business. There are now four pillars to our business, HIV, Cancer, GvHD, and diagnostics," added Dr. Pourhassan.

About PRO 140 (Leronlimab)
PRO 140 (leronlimab) 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 leronlimab (PRO 140), 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 leronlimab in combination with standard anti-retroviral therapies in HIV-infected treatment-experienced patients. The Company plans to seek FDA approval for leronlimab 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 leronlimab as a once-weekly monotherapy for HIV-infected patients, and plans to initiate a registration-directed study of leronlimab monotherapy indication, which if successful, could support a label extension. Clinical results to date from multiple trials have shown that leronlimab 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 leronlimab monotherapy can prevent viral escape in HIV-infected patients, with some patients on leronlimab monotherapy remaining virally suppressed for more than four years. CytoDyn is also conducting a Phase 2 trial to evaluate leronlimab for the prevention of GvHD and expects to initiate clinical trials with leronlimab 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 Company's metastatic triple negative breast cancer trial, the timing of the trial, its clinical focus, and the Company's other 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 leronlimab (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 timing of the metastatic triple negative breast cancer trial, (iv) the Company's ability to meet its debt obligations, if any, (v) the Company's ability to identify patients to enroll in its clinical trials in a timely fashion, (vi) the Company's ability to achieve approval of a marketable product, (vii) design, implementation and conduct of clinical trials, (viii) the results of the Company's 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 HIV that are viewed by medical professionals or patients as superior to the Company's 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 (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.