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CytoDyn Names Richard G. Pestell, M.D., Ph.D. as Vice Chairman of its Board of Directors

Dr. Pestell assumes an expanded strategic leadership role to advance Company initiatives in cancer and immunology

VANCOUVER, Washington, Jan. 07, 2019 (GLOBE NEWSWIRE) -- CytoDyn Inc. (OTC.QB: CYDY), a biotechnology company developing a novel humanized CCR5 monoclonal antibody for multiple therapeutic indications, announces that its board of directors elected Richard G. Pestell, M.D., Ph.D., M.B.A., F.A.C.P., F.R.A.C.P., Chief Medical Officer, and director to the additional position of Vice Chairman of the board of directors. As the Vice Chairman, he will advance and accelerate the Company's initiatives in seeking non-dilutive licensing opportunities in cancer and immunology. Dr. Pestell is an internationally renowned clinician and cancer researcher and a defining force in CCR5 antagonist research. He has a wealth of board experience and has served on several prestigious National and International boards. He was most recently Executive Vice President of Thomas Jefferson University and Director of the Sidney Kimmel Cancer Center. His expanded leadership role will further leverage the Company's ability to form strategic partnerships and further the clinical development of leronlimab (PRO 140) in cancer and immunology. Dr. Pestell was named to the Company's board of directors in November 2018 and was concurrently appointed Chief Medical Officer in connection with CytoDyn's acquisition of ProstaGene, LLC.

"We are honored to have Dr. Pestell serve as our Vice Chairman," said Nader Pourhassan, Ph.D., President and Chief Executive Officer of CytoDyn. "He is a world renowned cancer expert who has published over 500 papers. We envision the role of our Vice Chairman to serve as an ambassador capable of delivering our message of the potential for our platform drug leronlimab (PRO 140) worldwide. It just makes sense to elevate Dr. Pestell to this position, as we expect future results from our program to bring our technology into the spotlight. Dr. Pestell has the credibility on the world stage to represent the technology to other drug companies, potential collaborators, licensees and key opinion leaders. We also recognize his track record of success in overseeing cancer clinical trials for more than 13 years as the Director of two NCI -designated cancer centers. His expertise using CCR5 inhibitors in preclinical studies and the relationships he built while maintaining his commitment to excellence facilitated the approval from the FDA to proceed with our cancer trial. With his broad leadership experience and CCR5 expertise, CytoDyn has strengthened the development of leronlimab as a novel therapeutic for cancer metastasis."

Dr. Pestell has completed extensive research in numerous cancer indications and CCR5's role in the spread of cancer and has spoken publicly on the topic in multiple forums, including but not limited to TEDx talks (https://www.youtube.com/watch?v=98J1HgCm8wU). "Dr. Pestell's clinical and scientific background emphasizes the potential of leronlimab to prevent metastatic disease. If successful, it has the potential to change the way cancer is currently treated," said Scott Kelly, M.D., Chairman of the Board. "Having such an experienced and an excellent communicator as Vice Chairman allows the Company to multiply its awareness effort. We expect Dr. Pestell will be delivering paradigm changing news this coming year, as we ramp up the cancer program. We are energized by his commitment to expanding research with leronlimab into clinical trials and to further evaluate additional indications," added Dr. Kelly.

Dr. Pestell commented, "I am honored to accept the position of Vice Chairman of CytoDyn's board of directors. As I reflect on the new year ahead of us, there are many exciting potential new applications that CytoDyn intends to pursue for leronlimab (PRO 140). Given our previously published pre-clinical studies showing CCR5 inhibitors block breast and prostate cancer metastasis, I am most excited about exploring how CCR5 inhibition may block Triple Negative Breast Cancer (TNBC), through our recently approved clinical trial. Should the clinical trial prove successful, CCR5 inhibition in cancer could create a dramatic paradigm shift, with once weekly administration of leronlimab by the patients at home. Because of the recent studies we published demonstrating synergy between CCR5 inhibitors and several other drugs used for cancer treatment, we intend to develop strategic partnerships with specific pharmaceutical companies, and follow-on technologies. Because of the recent successful outcome of our 10 year retrospective clinical study in prostate cancer, we intend to pursue non-dilutive licensing agreements for our prostate cancer prognostic test."

About Leronlimab (PRO 140)
Leronlimab (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, leronlimab 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, leronlimab does not appear to interfere with the normal function of CCR5 in mediating immune responses. Leronlimab has been the subject of seven clinical trials, each demonstrating efficacy by significantly reducing or controlling HIV viral load in human test subjects. Leronlimab has been designated a "fast track" product by the FDA. The leronlimab 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 breast cancer. 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 leronlimab in the cancer

setting and has initiated a Phase 1b/2 human clinical trial, as recently approved in 2018 by the FDA.

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 leronlimab 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 leronlimab 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 half 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 initiated a clinical trial 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 clinical priorities, 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 Company’s expectations for its leading product candidate leronlimab (PRO 140) to demonstrate efficacy in non-HIV indications, (ii) the sufficiency of the Company’s cash position and the Company’s ongoing ability to raise additional capital to fund its operations, (iii) 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, (iv) the Company's ability to obtain FDA approval of PCaTest for use with prostate cancer patients; (v) the Company’s ability to meet its debt obligations, if any, (vi) the Company’s ability to identify patients to enroll in its clinical trials in a timely fashion, (vii) the Company’s ability to achieve approval of a marketable product, (viii) design, implementation and conduct of clinical trials, (ix) the results of the Company’s clinical trials, including the possibility of unfavorable clinical trial results, (x) the market for, and marketability of, any product that is approved, (xi) 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, (xii) regulatory initiatives, compliance with governmental regulations and the regulatory approval process, (xiii) general economic and business conditions, (xiv) changes in foreign, political, and social conditions, and (xv) 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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