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CytoDyn to Initiate 8 Pre-Clinical Animal Studies with Leronlimab (PRO 140) for Melanoma, Pancreatic, Breast, Prostate, Colon, Lung, Liver, and Stomach Cancer at an Estimated Cost of $1.5 million, which Could Lead to 8 Phase 2 Clinical Studies

VANCOUVER, Washington, Feb. 19, 2019 (GLOBE NEWSWIRE) -- CytoDyn Inc. (OTC.QB: CYDY), a biotechnology company developing a novel humanized CCR5 monoclonal antibody, leronlimab (PRO 140), for multiple therapeutic indications, announced that its new laboratory located in Philadelphia under the leadership of Professor Richard G. Pestell, M.D., Ph.D., M.B.A., F.A.C.P., F.R.A.C.P., Chief Medical Officer and Vice Chairman of CytoDyn, will conduct 8 pre-clinical studies on melanoma, pancreatic cancer, breast cancer, prostate cancer, colon cancer, lung cancer, liver cancer, and stomach cancer.

As part of CytoDyn's recent acquisition of ProstaGene, CytoDyn received control of a prestigious laboratory that operates under the guidance of Dr. Pestell. Most of the laboratory's personnel have prior experience related to Dr. Pestell's past cancer research. CytoDyn estimates the total cost of running the pre-clinical studies for these 8 cancers, the successful completion of which will be required to submit Phase 2 IND applications, is approximately $1.5 million (plus the cost of filing the IND).

"We believe CytoDyn's model to concurrently evaluate several opportunities in pursuit of multiple Phase 2 clinical trials in cancer, if the animal studies are positive, may represent a significant acceleration to create therapeutic benefit for cancer patients," said Dr. Nader Pourhassan, President and CEO of CytoDyn. "Exploring these opportunities with our new laboratory will not slow down the filing of our BLA or our monotherapy trial for HIV patients. We are also delighted that we have entered into discussions for commercializing leronlimab in 2020 and are currently considering a potential offer for royalties and milestone payments in connection with a commercialization partnership for HIV and GvHD indications," added Dr. Pourhassan.

"The receptor, CCR5, has been shown to function as a lynch pin in both the progression of cancer metastasis and HIV," said Dr. Pestell. "Most cancer deaths are linked to the metastasis not the primary tumor. Cancer can use CCR5 to spread the disease. Cancer metastasis has been reduced in animal studies and human pilot studies using CCR5 small molecule inhibitors. Leronlimab has a track record of safety, without serious adverse events related to leronlimab in over 670 patients from the HIV community. The safety record of leronlimab in the HIV community has been very important as we now begin treatment of

cancer patients. Since FDA recently approved the use of leronlimab in CytoDyn's triple negative breast cancer trial, the clinicians are working to ensure the trial is monitored carefully seeking interim results in Q2 2019. Metastatic triple negative breast cancer is a deadly disease, in which leronlimab is being studied together with the standard of care with the intent to improve outcomes including survival. This opportunity for treating the metastatic cancer community is only possible because of the extraordinary contributions of so many patients in the HIV community."

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. 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 vary materially from those contained in or expressed by such statements due to risks and uncertainties including: (i) the sufficiency of the Company's cash position, (ii) the Company's ability to raise additional capital to fund its operations, (iii) the Company's ability to meet its debt obligations, if any, (iv) the Company's ability to enter into partnership or licensing arrangements with third parties, (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) the design, implementation and conduct of the Company's 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 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 (xiv) various other matters, many of which are beyond the Company's control. The Company urges investors to consider specifically the various risk factors identified in its most recent Form 10-K, and any risk factors or cautionary statements included in any subsequent Form 10-Q or Form 8-K, filed with the Securities and Exchange Commission. Except as required by law, the Company does not undertake any responsibility to update any forward-looking statements to take into account events or circumstances that occur after the date of this press release.

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