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## **CytoDyn Treats First Patient in Phase 1b/2 Clinical Trial with Leronlimab (PRO 140) for Patients with Treatment-Naïve, Metastatic Triple-Negative Breast Cancer**

VANCOUVER, Washington, Sept. 27, 2019 (GLOBE NEWSWIRE) -- **CytoDyn Inc. (OTC.QB: CYDY)**, ("CytoDyn" or the "Company"), a late stage biotechnology company developing leronlimab (PRO 140), a CCR5 antagonist with the potential for multiple therapeutic indications announced today the injection of the first patient in a Phase 1b/2 clinical protocol with treatment-naïve metastatic triple-negative breast cancer (mTNBC).

The treatment of the first patient in mTNBC with leronlimab took place under the care of Dr. Jacob Lalezari, M.D. Dr. Lalezari is a scientific advisor to CytoDyn and current Chief Executive Officer of Quest Clinical Research. Dr. Lalezari has authored more than 75 peer-reviewed articles and served as a principal investigator in over 200 clinical trials with a particular focus on first-in-man and proof of concept studies. Dr. Lalezari is also principle investigator for CytoDyn's HIV monotherapy trial.

Results from this ongoing trial in mTNBC will dictate the Company's regulatory pathway, including the potential to seek Breakthrough Therapy Designation and accelerated approval with the U.S. Food and Drug Administration (FDA) for the use of leronlimab in mTNBC. Leronlimab has been granted Fast Track designation for mTNBC by the FDA based on a greater than 98% reduction of metastatic tumor volume in a murine xenograft model. Circulating Tumor Cells (CTC) will be evaluated in each patient every three weeks.

"There is a growing body of evidence about the role of CCR5 in cancer and, in particular, how CCR5 blockade by a drug like leronlimab could have a multitude of anti-tumor effects including inhibition of immune inhibitory T-cells and promotion of anti-tumor activity by macrophages. These activities are synergistic with the exciting new class of immunoncology drugs," stated Bruce Patterson, M.D., CEO of IncelIDX.

"Today marks a crucial milestone in our company's history, launching CytoDyn into clinical development in the oncology space," stated CytoDyn President and CEO, Nader Pourhassan, Ph.D. "It is important to note that leronlimab has completed nine successful clinical trials and has been dosed in over 800 patients in our HIV programs, without a single drug-related serious adverse event (SAE)," he continued. "With this safety record and results from multiple pre-clinical trials in various cancer indications, including mTNBC, and other indications like NASH and GvHD, we are optimistic about the potential of leronlimab to provide a new therapeutic option for the roughly 37,000 women that are diagnosed with triple-negative breast cancer each year in the United States. We wish to thank the women who have agreed to participate in our trials and endeavor to provide each of them with

clinical benefit. Along with our current mTNBC trial, CytoDyn will continue to enroll cancer patients under the expanded access program.”

### **About Leronlimab (PRO 140)**

The U.S. Food and Drug Administration (FDA) have granted a “Fast Track” designation to CytoDyn for two potential indications of leronlimab for deadly diseases. The first as a combination therapy with highly active antiretroviral therapy (HAART) for HIV-infected patients and the second is for metastatic triple-negative breast cancer. Leronlimab is an investigational humanized IgG4 mAb that blocks CCR5, a cellular receptor that is important in HIV infection, tumor metastases, and other diseases including non-alcoholic steatohepatitis (NASH). Leronlimab has successfully completed nine clinical trials in over 800 people, including meeting its primary endpoints in a pivotal Phase 3 trial (leronlimab in combination with standard anti-retroviral therapies in HIV-infected treatment-experienced patients).

In the setting of HIV/AIDS, leronlimab is a viral-entry inhibitor; it masks CCR5, thus protecting healthy T cells from viral infection by blocking the predominant HIV (R5) subtype from entering those cells. Leronlimab has been the subject of nine clinical trials, each of which demonstrated that leronlimab can significantly reduce or control HIV viral load in humans. 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 an important role in tumor invasion and metastasis. Increased CCR5 expression is an indicator of disease status in several cancers. Published studies have shown that blocking CCR5 can reduce tumor metastases in laboratory and animal models of aggressive breast and prostate cancer. Leronlimab reduced human breast cancer metastasis by more than 98% in a murine xenograft model. CytoDyn is therefore conducting a Phase 2 human clinical trial in metastatic triple-negative breast cancer and was granted Fast Track designation in May 2019. Additional research is being conducted with leronlimab in the setting of cancer and NASH with plans to conduct additional clinical studies when appropriate.

The CCR5 receptor appears to play a central role in modulating immune cell trafficking to sites of inflammation and may be important in the development of acute graft-versus-host disease (GvHD) and other inflammatory conditions. Clinical studies by others further support the concept 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 GvHD.

### **About CytoDyn**

CytoDyn is a biotechnology company developing innovative treatments for multiple therapeutic indications based on leronlimab, a novel humanized monoclonal antibody targeting the CCR5 receptor. CCR5 appears to play a key role in the ability of HIV to enter and infect healthy T-cells. The CCR5 receptor also appears to be implicated in tumor metastasis and in immune-mediated illnesses, such as 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. CytoDyn plans to seek FDA approval for leronlimab in combination therapy and plans to complete the filing of a Biologics License Application (BLA) in 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 has received clearance to initiate a clinical trial with leronlimab in metastatic triple-negative breast cancer. More information is at [www.cytodyn.com](http://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.

### **CONTACTS**

#### **Investors:**

Nader Pourhassan, Ph.D.  
President & CEO

[NPourhassan@CytoDyn.com](mailto:NPourhassan@CytoDyn.com)



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