

November 20, 2018



# USAN Council Assigns Leronlimab as the Official Name for CytoDyn's PRO 140

*BLA submission for first approval of leronlimab (PRO 140) on target for first quarter of 2019*

*Leronlimab (PRO 140) monotherapy trial results continue to impress with over 90% responder's rate*

VANCOUVER, Washington, Nov. 20, 2018 (GLOBE NEWSWIRE) -- CytoDyn Inc. (OTC.QB: CYDY), a biotechnology company developing a novel humanized CCR5 monoclonal antibody for multiple therapeutic indications, announces that the United States Adopted Names (USAN) Council has adopted leronlimab as the official name for PRO 140. Leronlimab is an investigational new drug and has not yet been approved for any indication.

"We are very excited to have PRO 140's new official name, leronlimab, assigned in the United States," said Dr. Nader Pourhassan, President and Chief Executive Officer of CytoDyn. "Leronlimab's first approval for its use in combination therapy is on target to have its Biologics License Application (BLA) filed by the end of the first quarter of 2019.

"As we recently announced, we are very pleased with the results of our monotherapy higher dose of leronlimab 700 mg showing an impressive responder's rate of over 90%," said Dr. Pourhassan. "We have two HIV populations that we are hopeful to have final approval for treating with leronlimab in 2019 (combination therapy) and 2020 (monotherapy).

Additionally, our leronlimab cancer study could have a read out by the first quarter of 2019 through the use of a circulating tumor cell (CTC) measurement, which can be done with a simple blood test.

"Leronlimab may represent a paradigm shift in the treatment of both HIV and cancer. For HIV, if our leronlimab monotherapy trial is successful, it will mark the first time a single agent therapy can replace the traditional three-component antiviral therapy. Regarding cancer, we look forward to commencing our trial."

CytoDyn is exploring partnering and licensing agreements for HIV treatment and intends to pursue them for cancer and other autoimmune diseases.

## **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 (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,

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 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 leronlimab 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 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 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](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, including statements regarding 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 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 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.

## **CONTACTS:**

**Investors:**

LHA Investor Relations

Jody Cain

310-691-7100

[jcain@lhai.com](mailto:jcain@lhai.com)



Source: CytoDyn Inc.