

September 6, 2019



## CytoDyn Announces Webcast for its Annual Meeting of Stockholders

VANCOUVER, Washington, Sept. 06, 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 that its annual meeting of stockholders on September 12, 2019 will be shared live through a webcast that will allow access to the audio portion of the meeting, along with management’s presentation.

Nader Pourhassan, Ph.D., President and CEO will provide an update on several initiatives, including BLA filing timeline, along with licensing and partnering opportunities. Dr. Pourhassan will also be joined by Jonah Sacha, Ph.D., Senior Science Advisor to the Company, who will discuss his research with leronlimab (PRO 140) as a potential therapeutic for HIV Pre-Exposure Prophylaxis (PrEP) and HIV cure. Dr. Sacha is an expert in HIV/AIDS research who serves on the National Institutes of Health Office of AIDS Research Advisory Council and leads a research laboratory in the Vaccine and Gene Therapy Institute and Oregon National Primate Research Center at the Oregon Health & Science University. In addition, Bruce Patterson, M.D., currently CEO and Founder of IncellDx, and former Medical Director of Virology at Stanford University Hospitals and Clinics, will comment on the role of targeting CCR5 for potential therapeutics and the recent agreement between IncellDX and CytoDyn.

**Date:** Thursday, September 12, 2019  
**Time:** 9:30 a.m. PT / 12:30 p.m. ET  
**Dial In:** For audio: 877-407-2986 or 201-378-4916

The live audio webcast may also be accessed via CytoDyn’s corporate website at [www.cytodyn.com](http://www.cytodyn.com) under the Investors section/IR Calendar and will be archived for two weeks. Web participants are encouraged to go to the website 15 minutes prior to the start of the meeting to register, download and install any necessary software. The webcast can also be accessed via the following link:

<https://78449.themediaframe.com/dataconf/productusers/cydy/mediaframe/32197/index1.html>

A replay of the annual meeting of stockholders will be available until September 26, 2019. To access the replay, interested parties may dial 877-660-6853 or 201-612-7415 and enter conference identification number 13691124.

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

The U.S. Food and Drug Administration (FDA) has granted a “Fast Track” designation to CytoDyn for two potential indications of leronlimab for deadly diseases. The first as a combination therapy with HAART for HIV-infected patients and the second is for metastatic triple-negative breast cancer (mTNBC). 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 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 >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 graft-versus-host disease (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 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. 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 (PRO 140) 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 (PRO 140) 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 and its ongoing ability to raise additional capital to fund its operations, (ii) the Company’s ability to complete the filing of a Biologics License Application (“BLA”) with the U.S. Food and Drug Administration (“FDA”) for leronlimab (PRO 140), as a combination therapy for the Human Immunodeficiency Virus (“HIV”), (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 for any clinical indication, (viii) the market for, and marketability of, any product that is approved, (ix) the Company’s ability to enter into partnership or licensing arrangements with third parties, (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 (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**

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Source: CytoDyn Inc.