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CytoDyn Will Attempt to Duplicate Berlin and London Patients' HIV Cure by Using Leronlimab During Bone Marrow Transplant for 5 HIV Patients Who also have Cancer

HIV monotherapy trials update: 215 patients completed almost one year of monotherapy. Only some were allowed to continue in extension arm; five patients reached almost 6 years. Twenty-five reached 2 to 4 years and 20 patients are 1 to 2 years

VANCOUVER, Washington, Aug. 17, 2020 (GLOBE NEWSWIRE) -- **CytoDyn Inc. (OTC.QB: CYDY)**, ("CytoDyn" or the "Company"), a late-stage biotechnology company gives full update on all of its HIV programs.

HIV Cure
The HIV co-receptor CCR5 has proven to be a key molecule in mediating HIV remission. The only two individuals functionally cured of HIV, one from London and the other from Berlin, received allogeneic stem cell transplantations from CCR5-deficient donors. However, because it is extremely rare to find a stem cell donor who lacks CCR5 and meets stringent MHC matching criteria, such an approach is unfeasible to cure HIV on a larger scale. CytoDyn believes its CCR5 blocking antibody, leronlimab, could be used in the setting of allogeneic stem cell transplantation to functionally convert a stem cell graft from a wildtype CCR5 stem cell donor into one from a CCR5 deficient donor, and thereby functionally cure the recipient of HIV.

CytoDyn plans to test this theory in a pilot clinical trial of five HIV patients with cancer who require bone marrow transplantation. Leronlimab will be used during the peri-transplant period to mimic a CCR5 deficient donor in order to achieve HIV cure.

HIV PrEP
As presented at the AIDS 2020 Virtual Conference, a pre-clinical study in the macaque model of HIV sexual transmission demonstrated leronlimab can prevent infection by blocking HIV's access to the CCR5 co-receptor. This protection is similar to that seen in individuals naturally CCR5 deficient and forms the rationale for use in HIV cure. CytoDyn believes leronlimab could be a once-a-month self-injectable, subcutaneous treatment for HIV PrEP and is in discussions with potential organizations to fund its next trial in HIV PrEP.

Monotherapy
Significantly, for the first time documented, of the 49 HIV patients who stopped their HIV medications and used leronlimab as a monotherapy, 25 have been in monotherapy trial for

two to four years and five patients for nearly or over six years. Monotherapy was successful for some of these patients by switching from 350 mg to a higher dose of 525 mg or 700 mg. The number of participants in the extension groups was limited due to costs.

The Company will submit manuscripts for two publications in regards to its findings.

Nader Pourhassan, Ph.D., President and Chief Executive Officer of CytoDyn, stated, “We now have four paths forward for use of leronlimab in the HIV indication for different populations. The first path is a combination therapy where we successfully completed a Phase 3 trial with statistically significant *p* value for our primary endpoint. CytoDyn is awaiting a Type A meeting with the FDA for this treatment. Second is our monotherapy; we will discuss the potential approval path for label expansion at the time of our Type A meeting. Third is our PrEP study to examine the use of leronlimab for once-a-month self-injection for HIV prevention. Our fourth path is an HIV-Cure, where 5 patients will be put to test to duplicate the Berlin and London patients’ HIV functional cure.”

About Leronlimab (PRO 140)
The FDA has granted a Fast Track designation to CytoDyn for two potential indications of leronlimab for critical illnesses.

The first as a combination therapy with 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 NASH. Leronlimab has completed nine clinical trials in over 800 people and met its primary endpoints in a pivotal Phase 3 trial (leronlimab in combination with standard antiretroviral 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 could 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 may play a role in tumor invasion, metastases, and tumor microenvironment control. 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 1b/2 human clinical trial in metastatic triple-negative breast cancer and was granted Fast Track designation in May 2019.

The CCR5 receptor appears to play a central role in modulating immune cell trafficking to sites of inflammation. It may be crucial 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 support further the concept that the CCR5 receptor on engrafted cells is critical for the development of acute GvHD, blocking the CCR5 receptor from recognizing specific 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 late-stage 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 critical 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 immune-mediated illnesses, such as GvHD and NASH.

CytoDyn has successfully completed a Phase 3 pivotal trial with leronlimab in combination with standard antiretroviral therapies in HIV-infected treatment-experienced patients. The Company has requested a Type A meeting with the FDA to discuss the FDA's request for additional information in order to resubmit its Biologics License Application for this HIV combination therapy.

CytoDyn is also conducting a Phase 3 investigative trial with leronlimab as a once-weekly monotherapy for HIV-infected patients. CytoDyn plans to initiate a registration-directed study of leronlimab monotherapy indication. If successful, it 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. No drug-related serious site injection reactions reported in about 800 patients treated with leronlimab and no drug-related SAEs reported in patients treated with 700 mg dose of leronlimab. Moreover, a Phase 2b clinical trial demonstrated that leronlimab monotherapy can prevent viral escape in HIV-infected patients; some patients on leronlimab monotherapy have remained virally suppressed for more than five years.

CytoDyn is also conducting a Phase 2 trial to evaluate leronlimab for the prevention of GvHD and a Phase 1b/2 clinical trial with leronlimab in metastatic triple-negative breast cancer. 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. Forward-looking statements specifically include statements about leronlimab, its ability to have positive health outcomes, the possible results of clinical trials, studies or other programs or ability to continue those programs, the ability to obtain regulatory approval for commercial sales, and the market for actual commercial sales. 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.

CYTODYN CONTACTS
Investors:
Michael Mulholland
Office: 360.980.8524, ext. 102
Mobile: 503.341.3514
mmulholland@cytodyn.com

Source: CytoDyn Inc.