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CytoDyn Announces Acceptance of Leronlimab (PRO 140) Data for Presentation at the Conference on Retroviruses and Opportunistic Infections (CROI) in March 2020

Independent data from the PRESTIGIO Registry Study Group in Italy shows leronlimab inhibits multi-drug resistant HIV-1 viruses in Heavily Treatment-Experienced (HTE) patients

VANCOUVER, Washington, Nov. 18, 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 an abstract from the PRESTIGIO Registry Study Group showing that leronlimab was effective at inhibiting multi-drug resistant HIV-1 isolates from HTE patients was accepted for presentation at CROI. The HTE HIV-1-infected patients harbored documented 4-class resistances and were enrolled in the Italian PRESTIGIO Registry Study Group. The authors conclude that, in HTE patients with multi-drug resistance to HIV-1, all CCR5 tropic strains were fully susceptible to PRO 140.

PRESTIGIO is an Italian registry (http://www.registroprestigio.com) involving 40 clinical centers throughout Italy, coordinated by the IRCCS San Raffaele Hospital (Milan). The registry is performing medical research in a study involving HTE HIV-1-infected patients with a documented 4-class drug resistance (multi-drug resistance MDR), including novel treatment approaches.

"This completely independent research study on clinical isolates from patients with documented 4-class drug resistances demonstrates that leronlimab may play a key role in patients with very limited therapeutic options," stated CytoDyn President and CEO, Nader Pourhassan, Ph.D. "This is further support for our belief that leronlimab is positioned to change the treatment paradigm in HIV therapy," Dr. Pourhassan concluded.

This data, co-authored by Stefano Rusconi, M.D., et al., University of Milan, on behalf of the PRESTIGIO Registry Study Group, will be presented at the March 8-11, 2020 CROI meeting at the Hynes Convention Center, Boston, MA.

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 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 a vital 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. CytoDyn is conducting additional research with leronlimab in the setting of oncology and NASH with plans to conduct further clinical studies when appropriate.

The CCR5 receptor appears to play a central role in modulating immune cell trafficking to sites of inflammation. It 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 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 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 crucial 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 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. CytoDyn 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. Some patients on leronlimab monotherapy have viral suppression 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.

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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