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CytoDyn Announces Productive Conference Call with FDA Regarding First BLA Submission for Leronlimab (PRO 140) Combination Therapy at 700 mg Dose

Successful interim results in the 700 mg monotherapy arm prompted the FDA to allow CytoDyn to switch all remaining combination therapy patients from CD02-Extension study from 350 mg to 700 mg dose

CytoDyn is in negotiations for post-approval sales distribution channels with potential upfront payment to CytoDyn

VANCOUVER, Washington, Feb. 01, 2019 (GLOBE NEWSWIRE) -- CytoDyn Inc. (OTC.QB:CYDY), a biotechnology company developing new antibody therapies for combating human immunodeficiency virus (HIV) infection and potentially disrupting cancer metastasis, announces that it had a productive conference call meeting with the U.S. Food and Drug Administration (FDA) regarding its Biologics License Application (BLA) submission. This was the first follow-up meeting since its June 2018 pre-BLA meeting regarding the Company's planned submission of its BLA and the positive interim data of its 700 mg monotherapy trial. The FDA recognized that the higher dosage of 700 mg in the monotherapy trial had a much higher response rate than the 350 mg dose used in the combination therapy trial. In order to avoid a long delay in the BLA filing, the FDA agreed to accept safety data from 100 patients in the monotherapy trial with the 700 mg dose, which enables the BLA submission for the combination therapy to use 700 mg instead of the original 350 mg dose.

CytoDyn currently has 45 patients enrolled in monotherapy with 700 mg, 29 additional patients who have switched from lower doses to the 700 mg dose and over 40 patients currently in screening to initiate 700 mg dose arm of monotherapy trial. The FDA also gave CytoDyn permission to upgrade all ongoing patients who are currently on 350 mg in the combination therapy to 700 mg dose.

"We are extremely appreciative of the agency's guidance for the approval process for the world's first self-injectable antibody for HIV," said Nader Pourhassan, Ph.D., CytoDyn President and CEO of CytoDyn.

"The safety data requested by the FDA for 100 patients at the 700 mg dose was extremely favorable to our drug development timeline. We are also pleased to report that we have initiated planning meetings with potential commercialization partners to provide their distribution channels for sales of leronlimab immediately following our anticipated approval. The anticipated partnership structure may take the form of upfront investment in CytoDyn in

exchange for a royalty post approval. All the structures we are considering are in line with our desire to pursue non-dilutive financing options. We are also negotiating with several large manufacturing companies to add $500 million worth of inventory to our current commercial inventory for deferred payments after approval."

Dr. Pourhassan continued, "We believe we can realize significant revenue opportunities by 2020 assuming the first approval of leronlimab (PRO 140). CytoDyn has a platform technology in HIV, cancer, graft-versus-host disease (GvHD), and a prostate cancer prognostic test. We believe leronlimab will also positively affect many lives in the triple negative breast cancer population, which is an unmet medical need population and therefore, we are very hopeful for a very strong 2019 and expect to achieve many important milestones."

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 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 breast cancer. 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 has initiated a Phase 1b/2 human clinical trial, as recently approved in 2018 by the FDA.

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 half 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 initiated a clinical trial with leronlimab in metastatic triple-negative breast cancer in 2018. 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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