September 2, 2020

U.K. MHRA Grants Meeting to CytoDyn to Discuss Fast Track Approval of Leronlimab for COVID-19 Patients

U.S. FDA schedules Type A meeting with CytoDyn to discuss BLA filing for HIV

VANCOUVER, Washington, Sept. 02, 2020 (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 the Medicines & Healthcare product Regulatory Agency (MHRA) of the U.K. government requested a meeting with CytoDyn on September 9, 2020 to discuss the Company's request for Fast Track approval of leronlimab to treat COVID-19 patients with mild-to-moderate symptoms based upon the trial's Top-line Report and additional eIND data. On the suggestion of the MHRA, CytoDyn will submit its current Phase 3 CD12 study for severe-to-critical COVID-19 patients in the UK to the Urgent Public Health (UPH) Research scheme to receive possible financial support from the trial sites and the government, if the UPH deems the Company's CD12 trial an urgent health issue.

In addition, the U.S. Food and Drug Administration (FDA) advised the Company the agency has scheduled a Type A meeting on September 8, 2020, following the Company's receipt of the agency's written responses on September 1 concerning it Biologic License Application (BLA) for leronlimab as a combination therapy for highly treatment-experienced HIV patients. The FDA clarified the items it needed primarily related to dosage levels.

Nader Pourhassan, Ph.D., President and Chief Executive Officer of CytoDyn, stated, "We are very encouraged by the MHRA's considering fast track approval of leronlimab and granting us a meeting. In this meeting, CytoDyn will present a summary of its BLA for HIV in conjunction with our request for fast track approval for COVID-19 indication. We are also grateful to the MHRA for advising us about potential financial support from the sites and UK government for our CD12 study currently in process. We also look forward to meeting with the FDA to help expedite the resubmission of our BLA, as well as learning whether we receive Emergency Use Approval for leronlimab for COVID-19 or, alternatively, are required to proceed with a Phase 3 trial. Regardless, we are working diligently to ensure the availability of leronlimab worldwide to provide a potential benefit for patients infected with this terrible disease."

About Coronavirus Disease 2019
CytoDyn completed its Phase 2 clinical trial (CD10) for COVID-19, a randomized clinical trial for mild-to-moderate patients in the U.S. and submitted the trial's Top-line Report to the U.S. FDA for emergency use approval and to the U.K. MHRA to request Fast Track Approval. While enrollment continues in its Phase 3 randomized clinical trial for the severe-to-critically ill COVID-19 population in several hospitals throughout the U.S., an interim analysis on the

first 195 patients will be performed in approximately four weeks with results anticipated in mid-October.

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 indication is 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

FDA has agreed to provide written responses to the Company's questions concerning its recent Biologics License Application by September 4, 2020, in lieu of a Type A teleconference meeting 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 six 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
mmulholland@cytodyn.com

Source: CytoDyn Inc.