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CytoDyn and the Mexican National Institutes of Health Participate in a Collaborative Study of Leronlimab for the Treatment of Severe/Critical COVID-19 Population

The study is anticipated to consist of approximately thirty patients with potential involvement of the NIH of Mexico in other CytoDyn trials

VANCOUVER, Washington, May 19, 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, today announced it will be coordinating with the NIH of Mexico and providing leronlimab for a trial for the severe/critical COVID-19 population in Mexico with the potential to collaborate on further CytoDyn COVID-19 trials.

CytoDyn is currently enrolling a Phase 2b/3 clinical trial for 390 patients, which is a randomized, placebo-controlled with 2:1 ratio (active drug to placebo ratio). CytoDyn is also enrolling a Phase 2 randomized clinical trial with 75 patients in the mild-to-moderate COVID-19 population. CytoDyn has been granted more than sixty emergency Investigational New Drug (eIND) authorizations by the U.S. Food and Drug Administration (FDA) and plans to provide clinical updates for this patient population later in the week.

"We look forward to evaluating leronlimab as a treatment option for patients of COVID-19. We have seen the devastation of this disease on the citizens of Mexico and are looking forward to providing effective treatment options to mitigate the devastation of COVID-19," said Dr. Gustavo Reyes Terán, head of the Coordinating Commission of National Institutes of Health and High Specialty Hospitals of Mexico, an organization that coordinates the main institutions of medical care and public research in the country.

"The NIH of Mexico is committed to help alleviate human suffering and mortality of Mexican citizens. The Metropolitan Area of the Valley of Mexico has a population of approximately 21.5 million people and the contagious nature of COVID-19 is relentless. We look forward to working with the NIH of Mexico to rapidly commence with the proposed study. We also believe that this study results, along with the ongoing Phase 2 study, could establish a path for quick approval in Mexico for use of leronlimab in COVID-19 patients," said Nader Pourhassan, Ph.D., President and Chief Executive Officer of CytoDyn.

About Coronavirus Disease 2019

CytoDyn is currently enrolling patients in two clinical trials for COVID-19, a Phase 2

randomized clinical trial for mild-to-moderate COVID-19 population in the U.S. and a Phase 2b/3 randomized clinical trial for severe and critically ill COVID-19 population in several hospitals throughout the country.

SARS-CoV-2 was identified as the cause of an outbreak of respiratory illness first detected in Wuhan, China. The origin of SARS-CoV-2 causing the COVID-19 disease is uncertain, and the virus is highly contagious. COVID-19 typically transmits person to person through respiratory droplets, commonly resulting from coughing, sneezing, and close personal contact. Coronaviruses are a large family of viruses, some causing illness in people and others that circulate among animals. For confirmed COVID-19 infections, symptoms have included fever, cough, and shortness of breath. The symptoms of COVID-19 may appear in as few as two days or as long as 14 days after exposure. Clinical manifestations in patients have ranged from non-existent to severe and fatal. At this time, there are minimal treatment options for COVID-19.

About Leronlimab (PRO 140) and BLA Submission for the HIV Combination Therapy
The 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. 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, including meeting 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.

The Company filed its BLA for Leronlimab as a Combination Therapy for Highly Treatment Experienced HIV Patients with the FDA on April 27, 2020, and submitted additional FDA requested clinical datasets on May 11, 2020. After the BLA submission is deemed completed, the FDA sets a PDUFA goal date. CytoDyn has Fast Track designation for leronlimab and a rolling review for its BLA, as previously assigned by the FDA, and the Company plans to request a priority review for the BLA. A priority review designation means the FDA’s goal is to take action on the marketing application within six months of receipt (compared with 10 months under standard review).

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. CytoDyn filed its BLA in April 2020 to seek FDA approval for leronlimab as a combination therapy for highly treatment experienced HIV patients, and submitted additional FDA requested clinical datasets on May 11, 2020. 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.

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