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CytoDyn Announces Clinically Significant Top-line Results from its Phase 2 Trial in Mild-to-Moderate COVID-19 Patients

Primary endpoint shows early clinical improvement in symptom score at Day 3 in patients receiving leronlimab

Leronlimab also demonstrated statistically significant improvement versus placebo in key secondary efficacy endpoint, National Early Warning Score 2 scale (NEWS2)

Results will be reported to the United States FDA, United Kingdom MHRA, and European Union regulatory agency, EMA

Management to hold conference call on August 12 at 1:00 pm PT - - details to follow

VANCOUVER, Washington, Aug. 11, 2020 (GLOBE NEWSWIRE) -- **CytoDyn Inc. (OTC.QB: CYDY)**, ("CytoDyn" or the "Company"), a late-stage biotechnology company announced today the Top-line results from its recently completed, randomized, double-blind, Phase 2 trial for COVID-19 patients with mild-to-moderate symptoms. CytoDyn will submit its Top-line Report for this trial to the U.S. Food and Drug Administration for review later this week. The Top-line Report revealed the following information:

Clinical improvement assessed by change in total clinical symptom score:

In patients with Total Clinical Symptom Score of ≥ 4 at baseline (higher scores equate to poorer health state): At Day 3, more subjects treated with leronlimab reported improvement in total clinical symptom score compared to the placebo group (90% on leronlimab arm vs. 71% on placebo). The subgroup analysis indicates that among patients with more symptoms at baseline, those who received leronlimab had a greater treatment effect than patients who received the placebo.

The National Early Warning Score 2 (NEWS2):

The National Early Warning Score (NEWS) is an objective scale developed by the Royal College of Physicians to identify patients at risk for rapid clinical deterioration requiring critical care intervention. NEWS2 (the latest version), is being used as an endpoint in several other COVID-19 clinical trials, including CytoDyn's severe-to-critical COVID-19 Phase 3 trial. It measures clinical parameters including respiratory rate, oxygen saturation, supplemental oxygen, temperature, systolic blood pressure, heart rate, and level of consciousness. In all treated patients, at the End of Treatment (or Day 14), patients in the leronlimab group were more than twice as likely to experience a beneficial improvement in scores compared to patients in the placebo group (50% vs 20%; $p=0.0223$).

Similar, statistically significant, results were observed at Day 3 and Day 14 in the analysis of per protocol population ($p < 0.03$ and $p < 0.02$, respectively).

Safety Endpoints:

The incidence, frequency, and severity of adverse events (AEs) and serious adverse events (SAEs) were lower in the leronlimab group compared to the placebo group. Patients treated with placebo were more than twice as likely to experience SAEs or AEs compared to patients treated with leronlimab.

Harish Seethamraju, M.D., Lead Principal Investigator at Montefiore Medical Center NY, stated, "The results demonstrate that CCR5 blockade by leronlimab given as a weekly subcutaneous injection in mild-to-moderate COVID-19 patients is reasonably safe and associated with rapid improvement in viral symptoms with fewer adverse events than when compared to placebo."

Nader Pourhassan, Ph.D., President and Chief Executive Officer of CytoDyn, stated, "In the mild- to-moderate population, it is important to have a therapeutic option for COVID-19 in patients who are showing signs of rapid clinical deterioration. Patients receiving leronlimab showed a statistically significant improvement using NEWS2 clinical parameters. We will make a case for immediate approval of leronlimab for this population of COVID-19 patients, not only in the U.S., but in the U.K. and other countries around the world."

Scott A. Kelly, M.D., Chief Medical Officer of CytoDyn, said, "We are thrilled with the results of leronlimab in mild-to-moderate COVID-19 patients. It is paramount to determine which patients will deteriorate and require critical care interventions, including patients at risk for ICU admission, cardiac arrest, or death within 24 hours. The NEWS2 aims to identify those patients most at risk. We are pleased that leronlimab showed a statistically significant result in a randomized, double-blinded study for NEWS2. The decreased probability in serious adverse events, as well as overall adverse events with leronlimab compared to placebo further supports the use of leronlimab as a treatment option for COVID-19."

Jacob P. Lalezari, M.D., Senior Science Advisor to CytoDyn, said, "Treatment with leronlimab demonstrated reductions in both serious adverse events, as well as predictors of pulmonary collapse in patients with mild-to-moderate COVID-19. We initiated the study hoping to reduce flu-like symptoms, such as fever, cough, and muscle aches. In the end, use of leronlimab was not only correlated with improved symptom scores in patients with measurable symptoms at baseline, but also provided significant and consequential benefits on far more serious endpoints. Demonstrating these efficacy signals in a population with mostly mild illness at study entry bodes well for leronlimab's activity in patients with more severe illness."

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. Enrollment continues in its Phase 3 randomized clinical trial for the severe-to-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 is believed to typically transmit person-to-person through respiratory droplets. 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)

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 and is working diligently to analyze and present new dosing information from a recently completed trial 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 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.

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