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CytoDyn's Phase 3 Trial Demonstrates Safety, a 24% Reduction in Mortality and Faster Hospital Discharge for Mechanically Ventilated Critically Ill COVID-19 Patients Treated with Leronlimab

VANCOUVER, Washington, March 08, 2021 (GLOBE NEWSWIRE) -- **CytoDyn Inc. (OTC.QB: CYDY)**, ("CytoDyn" or the "Company"), a late-stage biotechnology company developing Vyrologix™ (leronlimab-PRO 140), a CCR5 antagonist with the potential for multiple therapeutic indications, reported today the Phase 3 trial of leronlimab for the treatment of severe-to-critical patients with COVID-19 demonstrated continued safety, substantial improvement in the survival rate, and faster hospital discharge in critically ill COVID-19 patients. The trial's data has been reported to the U.S. Food and Drug Administration ("FDA"), the U.K.'s Medicines & Healthcare product Regulatory Agency ("MHRA") and Health Canada ("HC"), and the Company is in discussions with each to determine the best path forward for approval of leronlimab for treatment of COVID-19 in critically ill population. A manuscript of the trial's data is being prepared and will be submitted for publication in one or more major medical journals.

Highlights from the trial's data for this critically ill population include the following:

1. Survival benefit: There was a 24% reduction in all-cause mortality (primary endpoint of the study) in the leronlimab versus placebo.

2. Shortened time to recovery: The average length of hospital stay was reduced by 6 days for patients who received leronlimab with Standard of Care ("SoC") compared to placebo patients who received SoC only, with a statistically significant p-value of 0.005.

3. Discharge alive: In addition, patients who received leronlimab demonstrated an improved probability of "discharged alive" at Day 28 (28% versus 11%), a 166% better rate than in the placebo group.

Given the size of this critically ill population relative to the trial's size (62 out of 384 patients), the Company has concurrently filed an additional protocol with the FDA using the existing sites from its CD12 trial to quickly enroll patients in this population during the pendency of these ongoing regulatory discussions. The Company has continued to enroll patients (45) through the open-label arm of the CD12 trial and is working with regulators here and abroad to expedite this process.

Harish Seethamraju, M.D., Medical Director for the Mount Sinai Lung Transplantation Program, commented, “The CD12 trial results are very promising and leronlimab may be the only safe medication to help critically ill patients.”

Scott A. Kelly, M.D., Chairman and Chief Medical Officer, noted, “We believe this further supports CCR5 as a therapeutic target for immunomodulation and the importance of the disruption of the CCL5-CCR5 axis via leronlimab-mediated CCR5 blockade of pro-inflammatory leukocytes and reversal of the cytokine storm in critical COVID-19 patients.”

Nader Pourhassan, Ph.D., President and Chief Executive Officer of CytoDyn, commented, “Today, there are no approved drugs to effectively address the unmet medical need for critically ill COVID-19 patients. Our CD12 study demonstrates leronlimab is particularly effective in treating this patient population. We believe these results are the best results ever achieved for this population in a Phase 3 clinical trial. A recently approved IL-6 blocker used to treat severe to critical hospitalized COVID-19 patients requiring mechanical ventilation, reduced mortality by 2% compared to the placebo group. In contrast, leronlimab demonstrated a reduction of 24% in mortality compared to the SoC treated group, which is 12 times better in reducing all-cause mortality for critically ill COVID-19 patients. The Company is very excited about these results and is concurrently working with regulators here and abroad to expedite leronlimab’s approval to treat 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 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 11 clinical trials in over 1,200 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 by the FDA 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 was 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 granted orphan drug designation to leronlimab for the prevention of GvHD. Due to the lack of patients during the COVID-19 pandemic, the Company suspended its Phase 2 trial for acute 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 has been working diligently to refile its Biologics License Application (“BLA”) for this HIV combination therapy since receiving a Refusal to File in July 2020 and subsequently meeting with the FDA telephonically to address their written guidance concerning the filing. CytoDyn expects to refile its BLA in the first half of calendar year 2021.

CytoDyn has completed 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 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 provide 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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