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CytoDyn Completes Enrollment for Phase 3 Registrational Trial for 390 Patients with Severe-to-Critical COVID-19

CytoDyn is simultaneously finalizing an EUA application with the Philippine FDA with patient data from CD10 and recent eINDs for severe-to-critical patients

VANCOUVER, Washington, Dec. 15, 2020 (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, announced today it had reached full enrollment in its Phase 3 registrational trial for patients with severe-to-critical COVID-19. The 390-patient data will be analyzed in approximately 28 days, with expected results to be announced shortly thereafter.

On October 20, 2020, following review and recommendation by the Data Safety Monitoring Committee (DSMC) of data from 195 patients, the Company continued the trial without modification to achieve the primary endpoint. The DSMC also requested a second review of the data after 75% (or 293) of the patients were enrolled and completed a 42-day post-enrollment period. The Company has concluded it will be far more time efficient to forego the second interim analysis and to analyze the data on 390 patients and to provide final data to the U.S. Food and Drug Administration, Health Canada, U.K.'s MHRA, and Philippines FDA, as soon as it is available.

CytoDyn's Phase 2b/3 trial to evaluate the efficacy and safety of leronlimab for patients with severe-to-critical COVID-19 indications is a two-arm, randomized, double blind, placebo controlled, adaptive design multicenter study. Patients are randomized to receive weekly doses of 700 mg leronlimab, or placebo. Leronlimab and placebo are administered via subcutaneous injection. The study has three phases: Screening Period, Treatment Period, and Follow-Up Period. The primary outcome measured in this study is: all-cause mortality at Day 28. Secondary outcomes measured are: (1) all-cause mortality at Day 14, (2) change in clinical status of subject at Day 14, (3) change in clinical status of subject at Day 28, and (4) change from baseline in Sequential Organ Failure Assessment (SOFA) score at Day 14.

Nader Pourhassan, Ph.D., President and Chief Executive Officer of CytoDyn, commented, "We are very thankful for the concerted efforts by so many healthcare professionals to reach full enrollment so quickly in these trying times. To the best of our knowledge, we are the first company to complete a Phase 3 trial for COVID-19 severe-to-critical population. Currently, there are hundreds of thousands of patients around the globe with an immediate need for a safe and efficacious therapeutic to combat this horrific pandemic. Since the Philippine FDA has relaxed the criteria of EUA for any safe drug with any efficacy data, we will file our EUA as soon as the presidential order is implemented by the Philippine FDA with all of the

information we currently have available, which we believe could occur within the next couple of weeks. The Company is working diligently to ensure a sufficient supply of drug product is available to meet the urgent needs of patients.”

About Coronavirus Disease 2019

CytoDyn completed its Phase 2 clinical trial (CD10) for COVID-19, a double-blinded, randomized clinical trial for mild-to-moderate patients in the U.S. which produced statistically significant results for NEWS2. CytoDyn completed enrollment of 390 patients in its Phase 2b/3 randomized clinical trial for the severe-to-critically ill COVID-19 population and expects to release results in mid-January 2021.

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. Due to the lack of patients during the COVID-19 pandemic, the Company is closing down 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. The FDA met telephonically with Company key personnel and its clinical research organization and provided written responses to the Company's questions concerning its recent Biologics License Application ("BLA") for this HIV combination therapy in order to expedite the resubmission of its BLA filing for this indication.

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 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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