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FDA Resumes eIND Approval for Severe-to-Critical COVID-19 Patients Use of Vyrologix™ (leronlimab) Following Full Enrollment in CytoDyn's Phase 3 Trial

FDA's decision will enable CytoDyn to respond to ongoing requests for leronlimab until Phase 3 trial data is unblinded

VANCOUVER, Washington, Dec. 22, 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 a treating physician has received authorization from the U.S. Food and Drug Administration ("FDA") to administer leronlimab for a COVID-19 patient under emergency IND (eIND).

Nader Pourhassan, Ph.D., President and Chief Executive Officer of CytoDyn, commented, "We are very thankful the FDA is allowing severe-to-critical COVID-19 patients access to Vyrologix™ (leronlimab) again under eIND while we await the unblinding of data from our recently completed Phase 3 registrational trial. We are receiving daily requests from families seeking our drug for a loved one with COVID-19. In recent months, leronlimab received more than 60 eIND authorizations from the FDA, and during the pendency of our COVID-19 trials, we deferred seeking authorizations for eINDs in order to accelerate the pace of enrollment. Now that enrollment has been completed, we are pleased to be able to assist once again and remain hopeful the upcoming results of our Phase 3 trial will enable leronlimab to be more readily available for severe-to-critical COVID-19 patients."

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.

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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