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# CytoDyn Reaches Enrollment Target of 293 Patients for 2nd DSMC Interim Analysis of Phase 3 COVID-19 Trial and Expects to Enroll the Remaining 97 Patients in the Next Few Weeks to Complete the Trial This Year

*Concurrently, CytoDyn is working diligently with the FDA to initiate its Phase 2 COVID-19 Long Hauler Trial, with more than 100 volunteers wanting to enroll*

VANCOUVER, Washington, Nov. 23, 2020 (GLOBE NEWSWIRE) -- **CytoDyn Inc. (OTC.QB: CYDY)**, ("CytoDyn" or the "Company"), a late-stage biotechnology company developing Vyrologix™ (Ieronlimab-PRO 140), a CCR5 antagonist with the potential for multiple therapeutic indications, announced today it has reached enrollment of 293 patients in its Phase 3 trial for COVID-19 patients with severe-to-critical symptoms, thereby meeting the requested criteria for a second interim efficacy analysis by the Data Safety Monitoring Committee (DSMC).

After the first interim analysis, the DSMC requested a second interim analysis of all data after enrollment had reached 293 patients or 75% of the total patients for the trial. Approximately five weeks ago, the DSMC completed the first interim analysis on 195 patients (or 50% of the 390 planned patients) and recommended the trial continue without modification to achieve the primary endpoint and requested another interim analysis when enrollment reached 75% level (or 293 patients) to review patient mortality and other clinical outcome data.

Nader Pourhassan, Ph.D., President and Chief Executive Officer of CytoDyn, commented, "In addition to filing our biologics license applications in Canada and the U.K. for HIV, the Company is in full swing to obtain full enrollment in the Phase 3 COVID-19 trial before year end and initiate our Phase 2 trial for COVID-19 patients with multiple long-hauler symptoms and perhaps complete enrollment in 4-6 weeks. On another front, CytoDyn is also about to enroll its first patient in the NASH trial this month. We are very appreciative of the all-out effort by our clinical operations team (especially Mr. Brian Brothen, the Company's SVP of Global Oncology, and Dr. Kush Dhody from Amarex) and the clinical sites to expedite enrollment in this important trial and are hopeful the DSMC can complete their second interim analysis as quickly as possible. We continue to advance enrollment, without any pause to achieve the trial's planned 390 patients and we are currently evaluating the ability to conduct an interim analysis as soon as possible. In the meantime, if the pace of enrollment we have experienced in the last two weeks continues, we will have the CD12

enrollment completed before the end of the year. These are exciting times for the Company and I am honored to be working alongside such dedicated co-workers.”

### **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. Enrollment continues in its Phase 2b/3 randomized clinical trial for the severe-to-critically ill COVID-19 population in several hospitals and clinics throughout the U.S., which are identified on the Company’s website under the “Clinical Trial Enrollment” section of the homepage; an interim analysis on the first 195 patients was conducted mid-October and is expected to occur again now that the Company has reached enrollment of 293 patients.

### **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.

## **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 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](http://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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