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CytoDyn's Long-Haulers COVID-19 Trial Enrolled 20 Patients Within 10 Days; Enrollment to be Completed This Month

VANCOUVER, Washington, March 11, 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, announced today 20 patients have been enrolled and dosed in the first 10 days of its Phase 2 trial for COVID-19 long-haulers symptoms. The trial is designed to enroll 50 patients.

In summary, each patient will receive eight weekly doses followed by four weeks of safety evaluation. The endpoint measure will be at Day 56 with the trial data expected by mid-summer of 2021.

This trial is a Phase 2, randomized, double blind, placebo-controlled study to evaluate the efficacy and safety of leronlimab in patients experiencing prolonged coronavirus disease 2019 (COVID-19) symptoms (long-haulers).

Christopher Recknor, M.D., Vice President, Clinical Development, noted, "This trial represents a potential solution for many patients with post-acute sequalae from COVID-19 (PASC) known as long-haulers where currently no treatment is available. Patients in the trial have had lingering symptoms for over 12 weeks and they need help. We are looking at sophisticated biomarkers that will help us identify who benefits and why. This group of afflicted patients may represent a signal for all those who have had other post-viral complications and have lost their quality of life since the virus. It is of interest that patients with chronic fatigue present with similar complaints as those with PASC. In our CD10 COVID mild-to-moderate trial with leronlimab, we noted a reduction in adverse events or symptoms including fatigue, diarrhea, chest pain, fatigue, muscle weakness, and anxiety in treated vs. placebo groups. Since the CD10 trial did not have a restriction on the time from diagnosis of when COVID was made, some patients were post-COVID several weeks and may have been in the initial stages of PASC. Our job is to use what we learned from prior trials and show that Vyrologix™ can help."

Nader Pourhassan, Ph.D., President and Chief Executive Officer of CytoDyn, commented, "We are pleased to initiate this much awaited trial. Our NASH trial has similarly enrolled 20 patients and is moving forward with rapid speed thanks to Dr. Chris Recknor, who is in charge of both programs. With strong CD12 results, NASH and long-hauler results not too far away, along with our BLA submission for HIV coming up, we are more confident than ever about the future of leronlimab for many indications. We are also equally very excited about our cancer trial and ready to file for a Breakthrough Therapy Designation meeting with the FDA this month."

Enrollment continues in the Phase 2 clinical trial for COVID-19 long-haulers in several hospitals and clinics throughout the U.S., which are identified on the Company's website at www.cytodyn.com under the "Clinical Trial Enrollment" section of the homepage. Center for Advanced Research & Education, LLC, owned by Dr. Recknor, is one of the clinical locations for the Company's Phase 2 trial. Dr. Recknor is not involved in trial operations or in recruiting patients for this trial at this site. The agreement with the Center for Advanced Research & Education was negotiated in the ordinary course of business and on terms that are comparable to the terms available to unrelated third parties.

About COVID-19 Long-Hauler Symptoms

According to a recent article from The Journal of the American Medical Associationand a study done by British scientists, researchers estimate about 10% of COVID-19 patients become long-haulers. Published studies and surveys conducted by patient groups indicate 50% to 80% of patients continue to have troublesome symptoms three months after the onset of COVID-19 — even after tests no longer detect virus in their body. The list of long-hauler symptoms is extensive and inconsistent. For some people, the lingering symptoms are nothing like the original symptoms when they were first infected with COVID-19. The most common long-hauler symptoms include: coughing, ongoing, sometimes debilitating, fatigue, body aches, joint pain, heart issues, shortness of breath, loss of taste and smell, difficulty sleeping, headaches and brain fog (cognitive impairment).

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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