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CytoDyn Files New Protocol with U.S. FDA for 4 Doses of Leronlimab for Critically Ill COVID-19 Patients with the Objective to Duplicate or Surpass 82% Survival Benefit with P-Value of 0.0233 Originally Achieved from Two Weeks of Treatment in CD12 Trial With 2 Doses

Trial commencement will be expedited by enrolling patients in Brazil, U.K., and Canada while immediate EUA requests are pursued in multiple countries

VANCOUVER, Washington, April 01, 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 that after several weeks of discussions with the U.S. Food and Drug Administration ("FDA") and analysis of CD12 trial data, and in particular the 82% survival results over placebo after two weeks of leronlimab treatment, with statistically significant p-value of 0.0233, the Company has filed a new protocol to extend treatment to four weeks. The Company will initiate patient enrollment in multiple countries, including Brazil, where there are over 20,000 COVID-19 patients in ICU. CytoDyn believes four weeks of leronlimab treatment to be sufficient to calm the cytokine storm and to have a positive effect on survival rate at 4 weeks and potentially 8 weeks.

Nader Pourhassan, Ph.D., President and Chief Executive Officer of CytoDyn, commented, "As recently reported, our further analysis of the CD12 trial data demonstrated a statistically significant 82% reduction in mortality at 14 days for critically ill COVID-19 patients with 400% improvement in clinical outcome based on ordinal scale with discharge rate much better in leronlimab with p-value statistically significant. These results were achieved with just two doses of leronlimab, one dose at day 0 and a second dose at day 7. The half-life of leronlimab is 10 days and with only 2 doses, it is impressive we observed a 24% survival benefit at 28 days in critically ill COVID-19 patients, which we believe is as good or better than any reported results achieved so far with any other product for the critically ill population of COVID-19. Based on these results, we believe an increased dosage regimen will result in an equal or greater mortality benefit."

About Leronlimab (PRO 140)
The U.S. Food and Drug Administration (FDA) granted CytoDyn Fast Track designation to explore two potential indications using leronlimab to treat HIV and metastatic cancer. The

first indication is combination therapy with HAART for HIV-infected patients, and the second is for metastatic triple-negative breast cancer (mTNBC). Leronlimab is an investigational humanized IgG4 mAb that blocks CCR5, a cellular receptor important in HIV infection, tumor metastases, and other diseases, including NASH (Nonalcoholic Steatohepatitis). Leronlimab has been studied in 11 clinical trials involving more than 1,200 people and met its primary endpoints in a pivotal Phase 3 trial (leronlimab combined with standard antiretroviral therapies in HIV-infected treatment-experienced patients).

Leronlimab is a viral-entry inhibitor in HIV/AIDS. It masks CCR5, thus protecting healthy T cells from viral infection by blocking the predominant HIV (R5) subtype from entering those cells. Nine clinical trials have demonstrated leronlimab could significantly reduce or control HIV viral load in humans. The leronlimab antibody appears to be a powerful antiviral agent with fewer side effects and less frequent dosing requirements than currently used daily drug therapies.

Cancer research has shown 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 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. As a result, CytoDyn is conducting two Phase 2 human clinical trials, one in mTNBC, which was granted Fast Track designation by the FDA in 2019, and a second in a basket trial which encompasses 22 different solid tumor cancers.

The CCR5 receptor appears to play a central role in modulating immune cell trafficking to sites of inflammation. After completing two clinical trials with COVID-19 patients (a Phase 2 and a Phase 3), CytoDyn initiated a Phase 2 investigative trial for post-acute sequelae of SARS COV-2 (PASC), also known as COVID-19 Long-Haulers. This trial will evaluate the effect of leronlimab on clinical symptoms and laboratory biomarkers to further understand the pathophysiology of PASC. It is currently estimated that between 10-30% of those infected with COVID-19 develop long-term sequelae. Common symptoms include fatigue, cognitive impairment, sleep disorders, and shortness of breath. If this trial is successful, CytoDyn plans to pursue clinical trials to evaluate leronlimab's effect on immunological dysregulation in other post-viral syndromes, including myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS).

CytoDyn is also conducting a Phase 2 clinical trial for NASH to evaluate the effect of leronlimab on liver steatosis and fibrosis. Preclinical studies revealed a significant reduction in NAFLD and a reduction in liver fibrosis using leronlimab. There are currently no FDA approved treatments for NASH. NASH is a leading cause of liver transplant. About 30 to 40 percent of adults in the U.S. live with NAFLD, and 3 to 12 percent of adults in the U.S. live with NASH.

About CytoDyn
CytoDyn is a late-stage biotechnology company developing innovative treatments for multiple therapeutic indications using 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 using leronlimab combined 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 the calendar year 2021.

CytoDyn also completed a Phase 3 investigative trial with leronlimab used 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 approval. Clinical results to date from multiple trials have shown that leronlimab can significantly reduce the viral burden in people infected with HIV. Moreover, a Phase 2 clinical trial demonstrated that leronlimab monotherapy could prevent viral escape in HIV-infected patients; several patients on leronlimab's Phase 2 monotherapy extension arm have remained virally suppressed for more than six years. There have been no strong safety signals identified in patients administered leronlimab in multiple disease spectrums, including patients with HIV, COVID-19 and Oncology.

CytoDyn is also conducting a Phase 2 clinical trial with leronlimab in mTNBC, a Phase 2 basket trial in solid tumor cancers (22 different cancer indications), Phase 2 investigative trial for post-acute sequelae of SARS COV-2, also known as COVID-19 Long-Haulers, and a Phase 2 clinical trial for NASH. CytoDyn has already completed two trial in COVID-19 patients (a Phase 2 and a Phase 3) and is in the process of conducting an additional COVID-19 Phase 3 trial for mechanically ventilated critically ill COVID-19 patients. 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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