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CytoDyn to Submit Newly Completed Topline Report of CD12 Trial Results to Regulatory Agencies in Multiple Countries including India and Philippines

Finalized data analysis shows CD12 trial reached almost all of its major secondary endpoints in a subpopulation (62 patients) of critically ill COVID-19

VANCOUVER, Washington, May 18, 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 it intends to submit the results of its newly completed topline report of its CD12 Phase 3 clinical trial data for severe to critically ill COVID-19 patients to various regulatory agencies including but not limited to agencies in India and the Philippines.

A summary of the new key findings from the data of the CD12 Phase 3 clinical trial results, included in the newly completed topline report, consists of the following:

Efficacy Leronlimab mortality better than placebo		**Safety** No safety issues in CD12 or CD10 clinical trials
CD12: Critically ill population (7-day)	78%	CD12: LL arm 21% less AE/patients (AE/all patients)
CD12: Critically ill population (14-day)	82%	CD12: LL arm 3% less SAE/patients (SAE/all patients)
CD12: Critically ill population (21-day)	50%	CD10: LL arm 59% less AE/patients (AE/all patients)
CD12: Critically ill population (28-day)	31%	CD10: LL arm 64% less SAE/patients (SAE/all patients)

Patients in the CD12 trial were administered only two doses of leronlimab, the first dose at day zero and the second dose at day seven, while results were measured for 28 days (every 7 days). The results in the table above indicate that from day zero to day seven, critically ill patients receiving leronlimab (on day zero) experienced a mortality rate 78% lower than patients receiving placebo. Further, patients receiving the second dose of leronlimab achieved maximum benefit of 82% less mortality. However, the effects diminished from day 14 to day 21 and from day 21 to day 28, as the mortality rate decreased to 50% and 31%, respectively. This, we believe, was due to patients not being administered leronlimab past day 7.

The secondary endpoints met with statistically significant p-values for the critically ill subpopulation (62 patients) were:

1) All-cause mortality at day 14 (p =0.0233)
2) Proportion of patients achieving a category of 6 or higher on a 7-point ordinal scale at days 14 and 28 (p=0.036 & 0.038)
3) Change in clinical status of subject at day 14 on a 7-point ordinal scale (p=0.02)
4) Length of hospital stay in days (p=0.005)

Nader Pourhassan, Ph.D., President and Chief Executive Officer of CytoDyn, stated, “We are very thankful for the opportunity to be able to conduct two very crucial clinical trials in Brazil for severe and critically ill COVID-19 patients, which we believe could result in a statistically significant p-value of our primary endpoint leading the way to a potential approval. Although we did not meet our primary endpoint in our CD12 clinical trial in the mITT population, we were still very pleased that we did meet almost all of our secondary endpoints in the critically ill subpopulation of COVID-19 patients. To the best of our knowledge, we are unaware of another drug or therapeutic which has reported results in the critically ill population, in a randomized controlled trial, remotely close to what we reported for the CD12 trial. We are very excited for the opportunity to receive our first approval in multiple countries in great need of leronlimab. We are very confident this approval will happen this year.”

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. There have been no strong safety signals identified in patients administered leronlimab in multiple disease spectrums, including patients with HIV, COVID-19 and Oncology.

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 and appears to be implicated in tumor metastasis and immune-mediated illnesses, such as NASH.

CytoDyn 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 or shortly thereafter.

CytoDyn also completed a Phase 2/b3 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. Several patients on leronlimab's Phase 2b/3 monotherapy extension arm have remained virally suppressed for more than six years.

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). 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.

CONTACTS

Investors:
Cristina De Leon
Office: 360.980.8524
cdeleon@cytodyn.com

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