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# CytoDyn's Leronlimab Decreased Mortality at 14 Days by 82% With Statistically Significant P-Value of 0.0233 Amongst Critically Ill COVID-19 Patients

*Clinical outcome improvement (based on ordinal scale) with leronlimab at day 14 was 400% better than placebo arm with p-value of 0.021*

VANCOUVER, Washington, March 30, 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, is pleased to announce further results from its CD12 trial of severe-to-critically ill patients with COVID-19.

Upon further statistical analysis of the critically ill population (hospitalized patients receiving invasive mechanical ventilation (IMV) or ECMO), it was revealed that when leronlimab was added to standard of care ("SoC"), leronlimab decreased mortality at 14 days by 82% (p=.0233, N=62). Patients who received leronlimab were over five times more likely to be alive at day 14 than those who received SoC only.

Furthermore, leronlimab administration was associated with a 400% improvement in the ranking on the 7-point ordinal scale at 14 days when given in conjunction with SoC (p=.021, N=62) in the critically ill population, which provides direct evidence of tangible patient improvement.

The Company believes this data provides an opportunity to expound upon the advice and expertise of our Key Opinion Leaders to optimize the dosing of leronlimab for further clinical benefit.

This analysis builds upon the previously released information from the Company's mITT analysis of CD12 showing:

- A clear benefit when leronlimab was used in addition to "commonly used COVID-19 treatments," in the primary endpoint of all-cause mortality at day 28 with an absolute risk reduction of death of 6.5% and a relative risk reduction of death of 28.1% (N=309, p=.0319).
- A clear benefit when leronlimab was used in combination with dexamethasone, in the primary endpoint of all-cause mortality at day 28 with an absolute risk reduction of death of 5.7% and a relative risk reduction of 26.0% (N=233, p=.0552).
- Length in hospital stay decreased by 5.5 days in the critically ill population (N=62, p=.005).

- A clear trend toward mortality benefit at day 28 with an absolute risk reduction of death of 20.9% and a relative risk reduction of death of 73% when leronlimab was used in addition to “commonly used COVID-19 treatments” in the critically ill population with an age ≤ 65 years old.
- A clear trend toward mortality benefit at day 28 with an absolute risk reduction of death of 16.3% and a relative risk reduction of death of 73.5% when leronlimab was used in addition to dexamethasone in the critically ill population ≤ 65 years old.

Nader Pourhassan, Ph.D., President and Chief Executive Officer of CytoDyn, commented, “We will expediently submit an update with the above 14-day benefit to the U.S. FDA, Health Canada, and MHRA and will work closely with regulators in other countries. The Company believes this new information bolsters the case for immediate use of leronlimab for critically ill patients. Furthermore, we believe these results suggest that to see maximum effect of leronlimab at day 28, we must use three to four doses of leronlimab and not just two doses, as was the case with CD12 (day zero and day 7 only).”

The Company will provide further updates next week in an investment community webcast.

**About Leronlimab (PRO 140)**
The FDA has granted a FastTrack designation to CytoDyn for two potential indications of leronlimab for critical illnesses. The first indication is 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 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 combined 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.

Research has shown that CCR5 may play a role in tumor invasion, metastases, and tumor microenvironment control in the setting of cancer. 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.

**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 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 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 the viral burden in people infected with HIV. No severe drug-related site injection reactions were reported in about 800 patients treated with leronlimab, and no drug-related SAEs were reported in patients treated with 700 mg of leronlimab. Moreover, a Phase 2b clinical trial demonstrated that leronlimab monotherapy could 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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