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CytoDyn to File Accelerated Rolling Review with MHRA and Interim Order (IO) with Health Canada for COVID-19

U.S. FDA Reviewing Protocol for More COVID-19 Critical Patients to be Enrolled to Support Potential EUA

CytoDyn submitted protocol to U.S. FDA for immediate enrollment of 140 critical COVID-19 patients with same sites as CD12 trial – enrollment to commence upon FDA comments

VANCOUVER, Washington, March 08, 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 multiple regulatory pathways for approval of leronlimab as a treatment for critical COVID-19 patients in the U.S., U.K. and Canada.

MHRA has told the Company it will accept more data from the open-label portion of the current CD12 trial. To date, an additional 46 patients have been enrolled, but the results have not yet been communicated to any agency.

The Company anticipates the Health Canada Interim Order (IO) could allow the Company to sell leronlimab in Canada, while additional critical COVID-19 patients are enrolled. These discussions are on going, and the Company has initiated the process to submit an IO with Health Canada.

The Company also confirms the U.S. FDA has received its protocol for enrolling 140 critically ill COVID-19 patients with the primary endpoint defined as length of hospital stay.

CytoDyn is pleased to show strong data for critically ill COVID-19 patients. Considering the fact that:

(1) A higher proportion of patients over 65 were enrolled in the leronlimab arm (33%) compared to the placebo arm (23%), and

(2) Of the 384 treated patients, 117 were over 65 with an overall mortality rate 3.5 times higher (42% - 49/117) than for patients under 65 (12% - 31/267).

Therefore, an "age adjustment" analysis was performed and consequently, the updated results from the primary endpoint analysis are as follows:

1) Statistically significant results (p-value = 0.0319) reported for the primary endpoint (all-cause mortality at Day 28) in participants receiving leronlimab + "commonly used COVID-19 treatments" compared to participants who received "commonly used COVID-19 treatments"

alone in the placebo group in the overall modified intent-to-treat ("mITT") population.

2) Statistically significant results (p-value = 0.0552) reported for the primary endpoint (all-cause mortality at Day 28) among participants who received dexamethasone as the prior or concomitant standard of care treatment ("SoC") for COVID-19, compared to patients who received dexamethasone (without leronlimab) as SoC therapy in the overall mITT population.

3) Amongst all patients in mITT, the primary endpoint (all-cause mortality at Day 28) was not statistically significant. When age adjustment was conducted, the primary endpoint was much closer to statistically significant value. Of note, the reduction of mortality in this population of 65 years and younger leronlimab arm had more than 30% less mortality than placebo and 9% less mortality in participants over 65.

With the age adjustment analysis in all other major secondary endpoints, there was consistent numerical superiority over the placebo group, with some secondary endpoints approaching statistical significance.

Nader Pourhassan, Ph.D., President and Chief Executive Officer of CytoDyn, commented, "We are grateful for the chance to help critically ill COVID-19 patients. We continue to be pleased with the results from over 80 EINDs, 394 patients in CD12, and another 46 patients in the continuation of CD12's open-arm access, as well as the results published in two different peer reviewed journals. I am humbled by comments from the families whose lives they believe were saved with leronlimab and we look forward to making leronlimab more readily available to treat patients with COVID-19 and many other indications we are working on. I'm excited to address our investment community on Monday and to congratulate our entire extended team for their tireless support of the leronlimab program."

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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