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CytoDyn Announces First Patient Enrolled in Phase 2 Trial for NASH

Preclinical results demonstrated leronlimab effectively inhibited fatty liver development

VANCOUVER, Washington, Dec. 02, 2020 (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 the first patient first visit metric was met for the Company's Phase 2 clinical trial for the treatment of nonalcoholic steatohepatitis (NASH). The Phase 2 trial is designed to test whether leronlimab may inhibit the devastating liver fibrosis associated with NASH.

As previously reported, the Company's preclinical study demonstrated strong positive data highlighting the potential of leronlimab in treating nonalcoholic fatty liver disease (NAFLD), a common precursor to NASH. Inhibition of CCR5 has been shown to be effective in reducing fibrosis in animal models of NASH liver fibrosis.

Nonalcoholic fatty liver disease (NAFLD) has become the most common cause of chronic liver disease in adults worldwide. There are currently no U.S. Food and Drug Administration (FDA) approved treatments for NASH, and it is expected to be the number one cause of liver transplants in 2020.[1] About 30 to 40 percent of adults in the U.S. are living with NAFLD, and 3 to 12 percent of adults in the U.S. are living with NASH.[2]

"NASH is found in 65% of HIV patients with chronic elevation of transaminases. HIV provides a window into a potential mechanism for fibrosis caused by CCR5 disease-promoting liver macrophages and hepatic stellate cells. This study is a 60-patient, multi-center, randomized, double-blind, placebo-controlled Phase 2 two-arm study to assess the efficacy of leronlimab in adult patients with NASH. The study uses advanced MRI technology to monitor fatty deposition via proton density fat fraction and fibrosis by CT1 analysis without invasive biopsy. The precision of this testing will optimize the success for showing CCR5 inhibition can improve NASH and NALFD," said Chris Recknor, M.D., Vice President Clinical Development of CytoDyn.

Nader Pourhassan, Ph.D., President and Chief Executive Officer of CytoDyn, commented, "We are advancing all potential indications of leronlimab as fast as safely possible. We believe leronlimab will be an important part of many therapeutics including HIV, cancer and now NASH. We also hope to play a critical role in reducing mortality in patients infected with COVID-19. We hope to have a conference call toward the latter part of next week and update our shareholders with our progress and timelines for bringing leronlimab to market in the U.K., Canada, and the U.S. As a pre-revenue public company, we are always mindful of funding. With leronlimab's many potential indications and finishing our quarter end with significant cash on hand, we believe we are well-positioned to move this Company forward.

We look forward to our newly appointed Chief Scientific Officer, Mahboob Rahman, M.D., Ph.D., sharing our clinical advance timelines, who has an excellent track record of successful license applications with the FDA."

About Nonalcoholic Steatohepatitis (NASH)
Nonalcoholic steatohepatitis (NASH) is a chronic liver disease characterized histologically by the presence of hepatic inflammation and cell injury (hepatocellular ballooning) due to hepatic fat accumulation (steatosis) equal or superior to 5 percent of hepatocytes. Unhealthy eating habits and lack of physical activity in the absence of excessive alcohol consumption contributes to the development of NASH. NASH can progress to high-burden conditions such as cirrhosis, end-stage liver disease, and hepatocellular carcinoma (HCC). NASH is expected to become the leading cause of liver transplantation by 2020 in the United States.[3] NALFD is the most common form of chronic liver disease, affecting about 30 to 40 percent of the population in the United States.[4] An estimated 3 to 12 percent of the adult population in the United States have NASH,[5] of which approximately 15 to 20 percent will likely progress to advanced fibrosis or cirrhosis.[6] Despite its very high burden, there are currently no approved pharmacological therapies for NASH. Available therapies focus solely on treating NASH comorbidities, such as obesity, type 2 diabetes mellitus (T2DM) and cardiovascular disease (CVD), while NASH management options focus on lifestyle changes, based on diet and exercise, and control of the associated comorbidities. Lifestyle changes have demonstrated the greatest benefit in improving steatosis and mild fibrosis; however, as patients with advanced fibrosis due to NASH are at a significantly higher risk of liver-related mortality, pharmacological treatments are urgently needed.[7]

About Coronavirus Disease 2019
CytoDyn completed its Phase 2 clinical trial (CD10) for COVID-19, a double-blinded, randomized clinical trial for mild-to-moderate patients in the U.S. which produced statistically significant results for NEWS2. Enrollment continues in its Phase 2b/3 randomized clinical trial for the severe-to-critically ill COVID-19 population in several hospitals and clinics throughout the U.S., which are identified on the Company's website under the "Clinical Trial Enrollment" section of the homepage; an interim analysis on the first 195 patients was conducted mid-October and may occur again now that the Company has reached enrollment of 293 patients.

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 nine clinical trials in over 800 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 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 is currently 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 has granted orphan drug designation to leronlimab for the prevention of 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. The FDA met telephonically with Company key personnel and its clinical research organization and provided written responses to the Company's questions concerning its recent Biologics License Application ("BLA") for this HIV combination therapy in order to expedite the resubmission of its BLA filing for this indication.

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 2 trial to evaluate leronlimab for the prevention of GvHD and 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 have 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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Source: CytoDyn Inc.