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## **CytoDyn Reports Preliminary Results from First Five Patients in Phase 2 NASH Open Label Leronlimab Trial. Lower Fatty Deposits in All 5 Patients by as Much as 45% and Lower Fibrosis in 4 Patients by as Much as 10% Compared to Baseline.**

VANCOUVER, Washington, Nov. 03, 2021 (GLOBE NEWSWIRE) -- **CytoDyn Inc. (OTCQB: CYDY)** ("CytoDyn" or the "Company"), a late-stage biotechnology company developing leronlimab, a CCR5 antagonist with the potential for multiple therapeutic indications, announced today preliminary results from the first five patients treated with leronlimab in its Phase 2 trial for NASH (nonalcoholic steatohepatitis) open label. These preliminary findings from five patients treated with leronlimab suggested fatty deposits were lowered on all 5 patients by as much as 45%, as compared to the baseline measurement. In addition, fibrosis was also lowered by as much as 10%, in 4 out of 5 patients as compared to the baseline measurement (one patient exhibited no change in fibrosis).

The Phase 2 trial for 90 patients 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.<sup>1</sup> 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.<sup>2</sup>

Chris Recknor, M.D., Senior Executive Vice President of Clinical Operations, commented, "We are encouraged by the preliminary results from the open label portion of our NASH trial. The CT1 reduction from baseline for these patients is approximately 40 msec, which would be consistent with an observed reduction in fibrosis on biopsy. We expect data lock in December with results from the 700 mg double blind placebo-controlled part 1 and the remaining part 2 open label with 350 mg. We are working on a new Phase 2b/3 protocol to include biopsy to start in January 2022 with our new CRO, Cato Research LLC (CATO SMS), which has extensive experience with NASH trials."

Nader Pourhassan, Ph.D., CytoDyn's President and Chief Executive Officer, concluded, "We believe these early findings represent a very significant therapeutic opportunity for patients suffering from this disease, encouraging us to aggressively pursue a NASH indication with potential for Breakthrough Therapy designation (BTD). Our team is currently preparing the BTD application for 350 mg arm, which could include 10 patients' data by mid-November. We are also very optimistic for our 700 mg arm, which was double blinded; and we hope to unblind the data and announce those results in early December."

### **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.<sup>3</sup> NALFD is the most common form of chronic liver disease, affecting about 30 to 40 percent of the population in the United States.<sup>4</sup> An estimated 3 to 12 percent of the adult population in the United States have NASH,<sup>5</sup> of which approximately 15 to 20 percent will likely progress to advanced fibrosis or cirrhosis.<sup>6</sup> 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.<sup>7</sup>

### **About Leronlimab**

The U.S. Food and Drug Administration (FDA) granted CytoDyn Fast Track designation to explore two potential indications using leronlimab to treat Human Immunodeficiency Virus (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 binds to CCR5, a cellular receptor important in HIV infection, tumor metastases, and other diseases, including nonalcoholic steatohepatitis (NASH). Leronlimab has been studied in 16 clinical trials involving more than 1,200 people and met its primary endpoints in a pivotal Phase 3 trial (leronlimab combined with HIV standard care in patients with multi-drug resistance to current available classes of HIV drugs).

Leronlimab, among various potential applications, is a viral-entry inhibitor in HIV/AIDS. It binds to CCR5, thus protecting healthy T cells from viral infection by blocking the predominant HIV (R5) subtype from entering those cells. Leronlimab does not work on other strains of HIV (for example X4), however, R5 is the most dominant strain of HIV. Five 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 (for example, through angiogenesis). 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 97% in a murine xenograft model. As a result, CytoDyn is conducting two clinical trials, one, a Phase 2 in mTNBC, which was granted Fast Track designation by the FDA in 2019, and a second, a Phase 2, basket trial which encompasses 22 different solid tumor cancers.

The CCR5 receptor plays 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 evaluated 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. 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. Pre-clinical studies revealed a significant reduction in NAFLD and a reduction in liver fibrosis using leronlimab. There are currently no FDA approved treatments for NASH, which 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 plays 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 patients who were heavily treatment-experienced individuals with limited treatment options. CytoDyn is working diligently to resubmit its Biologics License Application ("BLA") for this HIV combination therapy since receiving a Refusal to File in July 2020. In July 2021, CytoDyn announced that it had submitted a dose justification report to the FDA, an integral step in the resubmission process for its BLA, which it expects to complete during the first calendar quarter of 2022. CytoDyn also completed a Phase 2b/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 expansion approval. Clinical results to date from two trials have shown that leronlimab can maintain a suppressed viral load in a sub-population of R5 HIV patients who chose to switch from their daily pills regimen to once-a-week subcutaneous dose of leronlimab. Several patients on leronlimab's Phase 2b extension arm have remained virally suppressed for almost 7 years

and many patients in our Phase 2b/3 investigative trial are passing two and some four years of monotherapy with suppressed viral load.

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 a Phase 2 and Phase 3 trial for mild-to-moderate and severe-to-critical COVID-19 patients, respectively, for which CytoDyn did not meet its primary or secondary endpoints except for the secondary endpoint in the critically ill subpopulation. More information is at [www.cytodyn.com](http://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 regulatory determinations of leronlimab's efficacy to treat human immunodeficiency virus ("HIV") patients with multiple resistance to current standard of care, COVID-19 patients, and metastatic Triple-Negative Breast Cancer ("mTNBC"), among other cancer indications, by the U.S. Food and Drug Administration and various drug regulatory agencies in other countries; (ii) the Company's ability to raise additional capital to fund its operations; (iii) the Company's ability to meet its debt obligations; (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) legal proceedings, investigations or inquiries affecting the Company or its products; (xiii) general economic and business conditions; (xiv) changes in foreign, political, and social conditions; (xv) stockholder actions or proposals with regard to the Company, its management, or its board of directors; and (xvi) 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 subsequent Form 10-Qs and Form 8-Ks, 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.

## Important Information

CytoDyn has filed with the SEC a definitive proxy statement and associated BLUE proxy card in connection with the solicitation of proxies for the Company's 2021 Annual Meeting, which has been adjourned until November 24, 2021. Details concerning the nominees of the Company's Board of Directors for election at the 2021 Annual Meeting are included in the proxy statement. BEFORE MAKING ANY VOTING DECISION, INVESTORS AND STOCKHOLDERS OF THE COMPANY ARE URGED TO READ ALL RELEVANT DOCUMENTS FILED WITH OR FURNISHED TO THE SEC, INCLUDING THE COMPANY'S DEFINITIVE PROXY STATEMENT AND ANY SUPPLEMENTS THERETO, BECAUSE THEY CONTAIN IMPORTANT INFORMATION.

Investors and stockholders can obtain a copy of the definitive proxy statement and other documents filed by the Company free of charge from the SEC's website, [www.sec.gov](http://www.sec.gov). The Company's stockholders also can obtain, without charge, a copy of the definitive proxy statement and other relevant filed documents by directing a request by mail to CytoDyn Inc. at 1111 Main Street, Suite 660, Vancouver, Washington 98660.

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Source: CytoDyn Inc.