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CytoDyn Files an IND and a Phase 2 Protocol with the FDA for the Treatment of NASH with Leronlimab

VANCOUVER, Washington, Sept. 04, 2019 (GLOBE NEWSWIRE) -- **CytoDyn Inc. (OTC.QB: CYDY)**, ("CytoDyn" or the "Company"), a late stage biotechnology company developing leronlimab (PRO 140), a CCR5 antagonist with the potential for multiple therapeutic indications, announced today the filing of an IND and a Phase 2 clinical trial protocol with the FDA for the treatment of non-alcoholic steatohepatitis (NASH). Based on published reports of the involvement of CCR5 in the pathogenesis of NASH, and following the Company's recent announcement of positive preclinical data, the Phase 2 trial is designed to test whether leronlimab may control the devastating liver fibrosis associated with NASH.

"We are cautiously optimistic about the potential of leronlimab to provide a new therapeutic option for individuals diagnosed with NASH. We again thank the men and women who have agreed to participate in our trials," stated Nader Pourhassan, Ph.D., CytoDyn's President and CEO.

This is a 60-patient, multi-center, randomized, double blind, placebo-controlled Phase 2 study of the safety and efficacy of leronlimab (PRO 140) in adult patients with NASH. NASH is a chronic liver disease characterized histologically by the presence of hepatic inflammation and cell injury due to hepatic fat accumulation (steatosis) equal or superior to 5% of hepatocytes. NASH develops in the absence of excessive alcohol consumption but is linked to unhealthy eating habits and lack of physical activity.

About 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% of hepatocytes. NASH develops in the absence of excessive alcohol consumption but is linked to unhealthy eating habits and lack of physical activity. It is often referred to as metabolic disease of the liver. NASH can progress to high-burden conditions such as cirrhosis, end stage liver disease and hepatocellular carcinoma (HCC) is predicted that NASH will become the leading cause of liver transplantation by 2020 in the United States. It is the most common form of chronic liver disease, affecting about one-quarter of the population in the United States. An estimated 3-7% of the adult population develop NASH, of which approximately 15-20% progress to advanced fibrosis or cirrhosis. 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

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.

About Leronlimab (PRO 140)
The U.S. Food and Drug Administration (FDA) has granted a "Fast Track" designation to CytoDyn for two potential indications of leronlimab for deadly diseases. The first as a 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 that is important in HIV infection, tumor metastases, and other diseases including NASH. Leronlimab has successfully completed nine clinical trials in over 800 people, including meeting its primary endpoints in a pivotal Phase 3 trial (leronlimab in combination with standard anti-retroviral 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 can 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 plays an important role in tumor invasion and metastasis. 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 >98% in a murine xenograft model. CytoDyn is therefore conducting a Phase 2 human clinical trial in metastatic triple-negative breast cancer and was granted Fast Track designation in May 2019. Additional research is being conducted with leronlimab in the setting of cancer and NASH with plans to conduct additional clinical studies when appropriate.

The CCR5 receptor appears to play a central role in modulating immune cell trafficking to sites of inflammation and may be important 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 further support the concept that the CCR5 receptor on engrafted cells is critical for the development of acute GvHD and that blocking this receptor from recognizing certain immune signaling molecules is a viable approach to mitigating acute GvHD. The FDA has granted "orphan drug" designation to leronlimab for the prevention of graft-versus-host disease (GvHD).

About CytoDyn
CytoDyn is a 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 key 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 in immune-mediated illnesses, such as graft-vs-host disease (GvHD) and NASH. CytoDyn has successfully completed a Phase 3 pivotal trial with leronlimab in combination with standard anti-retroviral therapies in HIV-infected treatment-experienced patients. CytoDyn plans to seek FDA approval for leronlimab in combination therapy and plans to complete the filing of a Biologics License Application (BLA) in 2019 for that indication. CytoDyn is also conducting a Phase 3 investigative trial with leronlimab (PRO 140) as a once-weekly monotherapy for HIV-infected patients and, plans to initiate a registration-directed study of leronlimab monotherapy indication, which if successful, could support a label extension. Clinical results to date from multiple trials have shown that leronlimab (PRO 140) can significantly reduce viral burden in people infected with HIV with no reported drug-related serious adverse events (SAEs). Moreover, results from a Phase 2b clinical trial demonstrated that leronlimab monotherapy can prevent viral escape in HIV-infected patients, with some patients on leronlimab monotherapy remaining virally suppressed for more than four years. CytoDyn is also conducting a Phase 2 trial to evaluate leronlimab for the prevention of GvHD and has received clearance to initiate a 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. 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 and its ongoing ability to raise additional capital to fund its operations, (ii) the Company’s ability to complete the filing of a Biologics License Application (“BLA”) with the U.S. Food and Drug Administration (“FDA”) for leronlimab (PRO 140), as a combination therapy for the Human Immunodeficiency Virus (“HIV”), (iii) the Company’s ability to meet its debt obligations, if any, (iv) the Company’s ability to identify patients to enroll in its clinical trials in a timely fashion, (v) the Company’s ability to achieve approval of a marketable product, (vi) design, implementation and conduct of clinical trials, (vii) the results of the Company’s clinical trials, including the possibility of unfavorable clinical trial results for any clinical indication, (viii) the market for, and marketability of, any product that is approved, (ix) the Company’s ability to enter into partnership or licensing arrangements with third parties, (x) the existence or development of vaccines, drugs, or other treatments for infection with HIV 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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