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CytoDyn Initiates Pre-Clinical Study of Leronlimab (PRO 140) to Prevent NASH with The Cleveland Clinic's Dr. Daniel J. Lindner, M.D., Ph.D.

VANCOUVER, Washington, May 13, 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, announces an agreement with The Cleveland Clinic's Dr. Daniel Lindner, M.D., Ph.D. to test leronlimab's ability to prevent Non-Alcoholic Steatohepatitis (NASH) in humanized murine models. The goals of these exploratory pre-clinical studies are to establish the ability of leronlimab to prevent the progression of Non-Alcoholic Fatty Liver Disease (NAFLD) into NASH. Maraviroc (Pfizer's HIV drug) has been a subject of several positive studies in this field; thus, CytoDyn intends to pursue this opportunity. (https://academic.oup.com/jac/article/69/7/1903/2911132).

NAFLD is an inflammatory disease caused by the build-up of fat in hepatocytes (steatosis). In severe cases, NAFLD progresses into Non-Alcoholic Steatohepatitis (NASH). It is estimated that 30 to 40 percent of adults in the United States have NAFLD, while 3 to 12 percent of adults in the United States have NASH. If left untreated, NASH may progress to hepatocellular carcinoma and is expected to become the leading cause of liver transplantation by 2020. The U.S. Food and Drug Administration (FDA) has stated that "identifying therapies that will slow the progress or, halt, or reverse NASH and NAFLD will address an unmet medical need." Despite the growing awareness of NASH, it remains difficult to diagnose and there are currently no FDA-approved therapies.

Meanwhile, the CCR5 pathway has been shown in multiple clinical trials and in unrelated third-party research to be a potential key target in NASH. Leronlimab is a highly selective CCR5 inhibitor. In over 700 patients, leronlimab has not demonstrated hepatotoxicity associated with other CCR5 antagonists. In addition, leronlimab could provide less frequent dosing and the unique ability to potentially be used as a monotherapy or synergistically with other molecular compounds. Numerous studies of NASH with other CCR5 agents have shown anti-inflammatory and anti-fibrotic effects.

"NASH is a quickly growing global epidemic without an approved treatment in the U.S.," stated Dr. Daniel Lindner, M.D., Ph.D. with The Cleveland Clinic Department of Hematology and Oncology and Research. "We have successfully developed humanized murine NASH models and look forward to determining if leronlimab can offer potential breakthroughs in NASH inhibition."

"We are extremely fortunate and excited to partner with The Cleveland Clinic and Dr. Daniel

Lindner to explore the potential of leronlimab in the prevention of NASH," stated Dr. Nader Pourhassan, Ph.D., CytoDyn's President and CEO. "A successful proof-of-concept study of leronlimab in NASH will allow the company to immediately file with the FDA an IND and protocol for a Phase 2 trial, as we have done with other indications," continued Dr. Pourhassan. "We are encouraged with Pfizer's (Maraviroc) results in this field and we look forward to sharing the results of our study, as soon as it is available."

About Non-Alcoholic Steatohepatitis (NASH)
NASH is liver inflammation and damage caused by buildup of fat in the liver. Many people have buildup of fat in the liver and for most people it causes no symptoms. However, according to The NASH Education Program (https://www.the-nash-education-program.com/what-is-nash/key-figures/), up to 25.2% of the adult global population may have NAFLD and the prevalence of NASH is expected to increase 63% between 2015 and 2030. NASH is now on pace to become the leading cause of liver transplantation in the U.S. by 2020. NASH is similar to the kind of liver damage caused by heavy, long-term drinking. However, NASH occurs in people who do not abuse alcohol. World Journal of Gastroenterology estimates that the ongoing global persistence of obesity and increasing rate of diabetes are the leading drivers of the increase in prevalence of NASH. (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5743497/)

About Leronlimab (PRO 140)
The U.S. Food and Drug Administration (FDA) has granted a "Fast Track" designation to leronlimab as a combination therapy with HAART for HIV-infected patients and for metastatic triple-negative breast cancer. Leronlimab is an investigational humanized IgG4 mAb that blocks CCR5, a cellular receptor that appears to play multiple roles with implications in HIV infection, tumor metastases and immune signaling. Leronlimab has successfully completed nine Phase 1/2/3 clinical trials in over 700 people, including a successful pivotal Phase 3 trial in combination with standard anti-retroviral therapies in HIV-infected treatment-experienced patients.

In the setting of HIV/AIDS, leronlimab belongs to a new class of therapeutics called viral-entry inhibitors; 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 likely plays a central role in tumor invasion and metastasis and that increased CCR5 expression is an indicator of disease status in several cancers. Moreover, research has shown that drugs that block CCR5 can block tumor metastases in laboratory and animal models of aggressive breast and prostate cancer. CytoDyn is conducting additional research with leronlimab in the cancer setting and plans to initiate additional Phase 2 human clinical trials, in addition to triple-negative breast cancer, when appropriate.

The CCR5 receptor also appears to play a central role in modulating immune cell trafficking to sites of inflammation and may be crucial for 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, (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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