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CytoDyn Announces FDA Clearance to Proceed with Phase 2 Study of Leronlimab (PRO 140) and Regorafenib as a Combination Therapy for Metastatic Colorectal Cancer

VANCOUVER, Washington, Sept. 09, 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 that the FDA has allowed a Phase 2 study to proceed for combination therapy of leronlimab and Regorafenib in patients with metastatic colorectal cancer (mCRC). The study will be conducted by lead principal investigator, John L. Marshall, M.D., Director, The Ruesch Center for the Cure of GI Cancers Frederick P. Smith Endowed Chair, Chief, Hematology and Oncology Lombardi Comprehensive Cancer Center, Georgetown University Medical Center, Washington, D.C.

"We have completed our safety review of your application and have concluded that you may proceed with your proposed clinical investigation of Protocol number CD08_mCRC, entitled, "A Phase II Study of Leronlimab (PRO 140) in combination with Regorafenib in Patients with CCR5+, Microsatellite Stable (MSS), Metastatic Colorectal Cancer (mCRC)," as stated in the letter from the FDA.

The Phase 2 study is a single arm study with 30 patients designed to test the hypothesis that the combination of leronlimab, administered as a subcutaneous injection, and Regorafenib, administered orally, will increase progression-free survival in patients with CCR5-positive metastatic colorectal cancer.

"This is the third clinical program that CytoDyn has underway in the oncology space," stated CytoDyn President and CEO, Nader Pourhassan, Ph.D. "We recently announced the first injection of a patient with leronlimab to treat metastatic triple-negative breast cancer (mTNBC), through the expanded access program under the supervision of Jacob Lalezari, M.D. In addition, our Phase 1b/2 trial using leronlimab in treatment-naïve mTNBC patients is under the supervision of Massimo Cristofanilli, M.D., professor of Medicine in the Division of Hematology/Oncology at Northwestern University Feinberg School of Medicine."

"With results from multiple pre-clinical studies in various cancer indications, including mTNBC and mCRC, we are optimistic about the potential of leronlimab to provide a new therapeutic option for individuals diagnosed with invasive cancer each year in the United States. We again thank the patients who have agreed to participate in our trials," concluded Dr. Pourhassan.

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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