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U.K. MHRA Clears CytoDyn to File its BLA for Leronlimab as One Injection per Week for Combination HIV Therapy

VANCOUVER, Washington, Oct. 26, 2020 (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 Medicines & Healthcare product Regulatory Agency (MHRA) of the U.K. government has cleared CytoDyn to file its Biologics License Application (BLA) for leronlimab as a combination therapy for multi-drug resistance HIV patients in the U.K.

The MHRA's clearance for the BLA filing included a treatment regimen of one injection per week of 350 mg of the Company's product leronlimab, as contrasted to the dosage used in the Phase 3 clinical trial conducted in the U.S. for this indication of two consecutive injections of 175 mg per week. During a recent 2-hour meeting between the CytoDyn BLA team and the MHRA, the parties discussed in detail the primary components of the BLA filing: non-clinical, clinical and manufacturing. In connection with the manufacturing section, the Company confirmed it had the necessary one-year of stability data for a 350 mg dose of leronlimab for patients in need of this treatment.

Nader Pourhassan, Ph.D., President and Chief Executive Officer of CytoDyn, commented, "We are very pleased with the MHRA's decision to clear our BLA for filing and our team is finalizing the remaining details to ensure a complete filing very soon. We hope to receive notice of acceptance within two weeks of our filing. The MHRA also had questions about CytoDyn's recent COVID-19 Phase 3 severe-to-critical population interim analysis. We are very excited with all of the opportunities we are able to explore for leronlimab's potential indication in the U.S. and abroad. Should CytoDyn receive approval in the U.K. for HIV combination therapy, we will follow up immediately with a label expansion of monotherapy in U.K."

About Leronlimab's Ability to Cross Blood-Brain Barrier
The blood-brain barrier (BBB) mediates the communication between the periphery and the central nervous system (CNS). The BBB separates the circulation from the brain. It is a highly selective permeable border of endothelial cells and acts as a metabolic barrier, transport interface, and secretory body. The BBB prevents solutes in the circulating blood from non-selectively crossing into the central nervous system's extracellular fluid where neurons reside. The blood vessels that vascularize the central nervous system (CNS) possess unique functions. The BBB allows precise control of CNS homeostasis. It serves to allow for proper neuronal function and also protects the neural tissue from toxins and pathogens. Alterations of these barrier properties are an important component of central nervous system diseases.

An important recent discovery of leronlimab is the ability to cross the blood-brain barrier to treat diseases where CCR5 antagonism may benefit the central nervous system. In a study of HIV in macaques, it was determined that the administration of leronlimab resulted in approximately 70-75% CCR5 receptor occupancy in the frontal lobes, parietal lobes, and cerebellum. Independent research on CCR5 antagonism in central nervous system pathology has shown promise in various disease processes, including multiple sclerosis, Parkinson's disease, CNS tumors, traumatic brain injury, and stroke recovery.

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 throughout the U.S.; an interim analysis on the first 195 patients was conducted mid-October.

CytoDyn is currently conducting its Phase 2b/3 COVID-19 trial for patients with severe-to-critical indications in numerous hospitals and clinics across the U.S., which are identified on the Company’s website under the “Clinical Trial Enrollment” section of the homepage.

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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