



## **U.S. Food and Drug Administration (FDA) Grants Emergency IND for Two Coronavirus Patients Treated in New York with CytoDyn's Leronlimab**

**A leading academic medical center has administered the test medication, leronlimab, in two of their sickest COVID-19 patients. Neither patient has had any serious adverse reactions to leronlimab since it was administered. We are hopeful leronlimab will provide help to severely ill COVID-19 patients.**

VANCOUVER, Washington, March 19, 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 that two coronavirus patients were treated with the Company's investigational new drug, leronlimab. The treatment was administered at a leading medical center in the New York City area under an emergency Investigational New Drug (IND) recently granted by the U.S. Food and Drug Administration (FDA). Leronlimab is intended to serve as a therapy for patients who experience respiratory illness as a result of contracting the Coronavirus Disease 2019 (COVID-19). The treatment of these patients was not under the Company's proposed randomized controlled Phase 2 clinical trial protocol recently submitted to the FDA.

Bruce Patterson M.D., CEO of IncellDX and advisor to CytoDyn, added, "Leronlimab binds to the CCR5 receptor inhibiting the migration of macrophages and the release on inflammatory cytokines including TNF and IL-6. This release of cytokines is what is commonly referred to as the 'cytokine storm' and is believed to cause profound damage in the lungs in some patients. In addition, leronlimab can block Regulatory T cells (Tregs), which can inhibit the innate immune response against pathogens, into areas of inflammation. These combined mechanisms of action may reduce the morbidity and mortality in moderate to severe cases of COVID-19, preventing the acute respiratory distress syndrome associated with this highly destructive and potentially fatal disease."

Nader Pourhassan, Ph.D., president and chief executive officer of CytoDyn said, "We are very pleased that we have a potential treatment option for patients affected by COVID-19 infection. To be very clear, leronlimab does not kill the novel coronavirus. It acts as a CCR5 antagonist by blocking pro-inflammatory cytokines, which prevents cytokine storm and thus could be useful in treatment of COVID-19. Leronlimab is administered as a once-a-week injection. It has a strong safety profile demonstrated in nine clinical trials with over 800 people and is available for urgent treatment. If results are promising, we have leronlimab available for immediate use and the ability to scale production. We are open and willing to work with government agencies and pharmaceutical partnerships to assist in serving those in dire need of a treatment option for this devastating disease. We appreciate the FDA's prompt response and are working in full support of the treating medical team."

### **About Coronavirus Disease 2019**

The Coronavirus Disease 2019 (COVID-19) was identified as the cause of an outbreak of respiratory illness first detected in Wuhan, China. The origin of COVID-19 is uncertain and it is unclear how easily the virus spreads. COVID-19 is thought to be transmitted person to person through respiratory droplets, commonly resulting from coughing, sneezing and close personal contact. Coronaviruses are a large family of viruses, some causing illness in people and others that circulate among animals. For confirmed COVID-19 infections, symptoms have included fever, cough and shortness of breath. It is believed that symptoms of COVID-19 may appear in as few as two days or as long as 14 days after exposure, and that symptoms in patients have ranged from non-existent to severe and fatal. At this time, there are very limited treatment options for COVID-19.

### **About Leronlimab (PRO 140)**

The 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. 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 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 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 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. 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 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 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 the first quarter of 2020 for that indication. CytoDyn is also conducting a Phase 3 investigative trial with leronlimab 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 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 five 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](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. 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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