

March 8, 2020



# **CytoDyn Files IND and Protocol for Phase 2 Clinical Trial for Treatment of Patients with Coronavirus with Leronlimab (PRO 140)**

**Coronavirus Can Quickly Progress to Severe Pneumonia and Even Death Due to Immune Hyperactivity Including Acute Respiratory Distress Syndrome (ARDS); CytoDyn's Trial Focuses on Patients Who Develop Mild-To-Moderate Respiratory Illness After Contracting Coronavirus**

**CytoDyn Negotiating to Expedite Setup of Treatment Clinics in New York and San Francisco**

VANCOUVER, Washington, March 08, 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 the Company has submitted an investigational new drug (IND) application to the U.S. Food and Drug Administration (FDA) to conduct a Phase 2 clinical trial with leronlimab (PRO 140) as a therapy for patients who experience respiratory complications as a result of contracting the coronavirus disease 2019 (COVID-19).

Bruce Patterson M.D., CEO of IncellDX and advisor to CytoDyn explains: "Leronlimab inhibits migration of Tregs, which can inhibit the innate immune response against pathogens, into areas of inflammation. Most importantly, the migration of macrophages and the release of inflammatory cytokines including TNF and IL-6 (cytokine storm) is what causes the profound damage in the lungs in some patients. Leronlimab binding to CCR5 changes the macrophages migration and cytokine production. Taken together, these activities may reduce the morbidity and mortality in moderate to severe cases of COVID-19. IncellDx has developed a suite of diagnostics to monitor these effects of leronlimab on the immune system in these critical patients."

"Coronavirus deaths are linked to patients' immune systems that have an inflammatory response to the virus causing Acute Respiratory Distress Syndrome (ARDS). With ARDS, the entire lung is affected, unlike pneumonia where often only part of the lung is affected," said Nader Pourhassan, Ph.D., president and chief executive officer of CytoDyn. "Our scientists believe that our data in cancer patients indicated that leronlimab's role in blocking Tregs and macrophages demonstrates that leronlimab modulates the inflammatory response to more effectively provide effector function. With more than 840 patients treated with leronlimab in our clinical trials, we believe leronlimab could reduce the inflammation which contributes to ARDS, thereby potentially reducing morbidity and mortality rates in

coronavirus patients. If we can show a similar response in our current Phase 2 trial, then leronlimab could have a powerful impact on improving the prognosis for coronavirus patients. With leronlimab's Fast Track designation from the FDA for the treatment of HIV and mTNBC (triple-negative breast cancer), we are expediting the initiation of this trial to address the rapid spread of this disease and are eager to test this proof of concept in clinical trials as a potential treatment for coronavirus," added Dr. Pourhassan.

The following is a brief summary of excerpts from the Company's Phase 2 clinical trial protocol:

**Indication for Use:** Leronlimab is indicated for treatment of adult patients with mild-to-moderate symptoms of respiratory illness caused by coronavirus 2019 infection.

**Objective:** The purpose of this study is to assess the safety and efficacy of leronlimab administered as weekly subcutaneous injection in subjects with coronavirus 2019 infection.

**Primary Outcome (Endpoint) Measure:** Clinical Improvement based on change in total symptom score (for fever, myalgia, dyspnea and cough)

Note: The total score per patient ranges from 0 to 12 points. Each symptom is graded from 0 to 3 [0=none, 1=mild, 2=moderate, and 3=severe].

**Trial Design:** This is a Phase 2, single arm, open-label, multicenter study to evaluate the safety and efficacy of leronlimab (PRO 140) in patients with mild-to-moderate symptoms of respiratory illness caused by coronavirus 2019 infection. Leronlimab (PRO 140) will be administered subcutaneously as weekly dose of 700 mg.

The study will have three phases: Screening Period, Treatment Period, and Follow-Up Period.

**Treatment Period:** 4 weeks  $\pm$  allowed windows.

**Inclusion Criteria:**

1. Male or female adult  $\geq$  18 years of age at time of enrollment.
2. Laboratory confirmation of coronavirus 2019 infection by polymerase chain reaction (PCR) or other commercial or public health assay from any diagnostic sampling source.
3. Subjects with mild-to-moderate symptoms of respiratory illness caused by coronavirus 2019 infection
4. Clinically normal resting 12-lead ECG at Screening Visit or, if abnormal, considered not clinically significant by the Principal Investigator.
5. Subject (or legally authorized representative) provides written informed consent prior to initiation of any study procedures.
6. Understands and agrees to comply with planned study procedures.
7. Women of childbearing potential must agree to use at least one primary form of contraception for the duration of the study (acceptable methods will be determined by the site).

### **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.<sup>1</sup> 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 prior to exposure, and that

symptoms in patients have ranged from non-existent to severe and fatal. There are currently no known antiviral treatments effective at suppressing COVID-19.

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

The U.S. Food and Drug Administration (FDA) have 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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1. Novel Coronavirus 2019, Wuhan, China. (2020, January 24). Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/index.html>



Source: CytoDyn Inc.