CytoDyn Inc.

Fact Sheet

CYDY

SYMBOL

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CYTODYN

QUICK REFERENCE

CytoDyn Inc.
OTCQB: **CYDY**
Outstanding Shares: 432,112,458
Website: **www.CYTODYN.com**

BUSINESS SUMMARY

CytoDyn is currently enrolling patients in two clinical trials for COVID-19, a Phase 2 randomized clinical trial for mild-to-moderate COVID-19 population in the U.S. and a Phase 2b/3 randomized clinical trial for severe and critically ill COVID-19 population in several hospitals throughout the country.

SARS-CoV-2 was identified as the cause of an outbreak of respiratory illness first detected in Wuhan, China. The origin of SARS-CoV-2 causing the COVID-19 disease is uncertain, and the virus is highly contagious. COVID-19 typically transmits 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. The symptoms of COVID-19 may appear in as few as two days or as long as 14 days after exposure. Clinical manifestations in patients have ranged from non-existent to severe and fatal. At this time, there are minimal treatment options for COVID-19.

Leronlimab and BLA Submission for the HIV Combination Therapy

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 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 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.

CONTACT INFORMATION

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Recent Press Releases *(Headlines and Excerpts)*

CytoDyn to Prepare a Phase 3 Protocol to Submit to the FDA for a Three-Arm Comparative and Combination Trial of Leronlimab and Remdesivir

Three arms of this trial will be leronlimab, remdesivir, and leronlimab + remdesivir

May 18, 2020 -- CytoDyn Inc. announced it will be submitting a protocol to the U.S. Food and Drug Administration (FDA) for a factorial design trial to compare effectiveness of leronlimab versus remdesivir and in combination with remdesivir for the treatment of COVID-19.

Leronlimab was administered to more than sixty patients with COVID-19 under emergency Investigational New Drug (eINDs) authorizations granted by the FDA. Preliminary results from this patient population led to CytoDyn's Phase 2b/3 clinical trial for 390 patients, which is randomized, placebo-controlled with 2:1 ratio (active drug to placebo ratio). CytoDyn has also been granted a Phase 2 randomized clinical trial study in the U.S. for a Phase 2 randomized clinical trial for mild-to-moderate COVID-19 population in the U.S. CytoDyn plans to update the public regarding current eIND results later this week.

CytoDyn to Offer No-Cost Exploratory Laboratory Testing for Childhood Inflammatory Disease Associated with COVID-19

May 15, 2020 -- CytoDyn Inc. announced it is offering comprehensive cytokine profiling (including RANTES levels) through its diagnostic partner company, IncellDx, to help physicians understand the pathogenesis of Childhood Inflammatory Disease Related to COVID-19. These laboratory tests are exploratory in nature and not intended for clinical decision making.

CytoDyn Completed Submission of All Remaining Parts of Biologics License Application on May 11, 2020

CytoDyn Submits Requested Datasets to FDA for Biologics License Application

May 13, 2020 -- CytoDyn Inc. confirmed on May 11, 2020, it submitted all remaining parts of the Company's Biologics License Application ("BLA") for leronlimab as a combination therapy with HAART for highly treatment experienced HIV patients to the U.S. Food and Drug Administration ("FDA"). Pursuant to FDA guidelines, CytoDyn informed the FDA it had submitted a complete BLA for rolling review.

As a next step, the FDA will start reviewing the BLA for completeness and will make a filing decision. After the BLA submission is deemed completed, the FDA assigns a Prescription Drug User Fee Act (PDUFA) goal date. CytoDyn has Fast Track designation for leronlimab and a rolling review for its BLA, as previously assigned by the FDA, and the Company plans to request a priority review for the BLA. A priority review designation, if granted, means the FDA's goal is to take action on the application within six months of receipt (compared with 10 months under standard review).

Novant Health Initiates Phase 2b/3 Trial with CytoDyn's Leronlimab for Severely and Critically Ill COVID-19 Patients

May 07, 2020 -- CytoDyn Inc. announced that Novant Health is initiating patient enrollment in CytoDyn's Phase 2b/3 trial for severely and critically ill COVID-19 patients.

Leronlimab has been administered to 54 severely and critically ill COVID-19 patients thus far under Emergency Investigational New Drug (EINDs) authorizations granted by the U.S. Food and Drug Administration (FDA). Preliminary results from this patient population led to the FDA's recent clearance for CytoDyn's Phase 2b/3 clinical trial for 390 patients, which is randomized, placebo-controlled with 2:1 ratio (active drug to placebo ratio). Patients enrolled in this trial are expected to be administered leronlimab for two weeks with the primary endpoint being the mortality rate at 28 days and a secondary endpoint of mortality rate at 14 days. The Company will perform an interim analysis on the data from 50 patients.

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