CytoDyn Inc.

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CytoDyn sees positive test results from seven coronavirus patients in New York treated with its drug Leronlimab

CytoDyn Inc (OTCMKTS:CYDY) shared positive test results on Friday from seven coronavirus (COVID-19) patients who were treated with the company's drug leronlimab at a leading medical center in the New York City area.

The use of leronlimab, which has other therapeutic indications as a treatment for HIV and certain breast cancers, is being administered under an emergency Investigational New Drug Application (IND) recently granted by the US Food and Drug Administration.

The company said the diagnostics company IncellDx's evaluation of test results from the first four patients show "immunological benefits within three days" following treatment with leronlimab on all four patients, and "lower level of cytokine storm, especially IL-6 and TNF-?, which were reduced significantly."

READ: CytoDyn sees two more coronavirus patients in New York treated with its drug leronlimab

Specifically, leronlimab is intended to serve as a therapy for patients experiencing respiratory complications as a result of the virus.

Bruce Patterson, an advisor to CytoDyn and CEO of IncellDx, said his company has worked to validate leronlimab as a treatment option by developing specific diagnostic tests to determine the potential and dosing of leronlimab in severe coronavirus cases.

"We found that patients with severe COVID-19 disease are in the midst of immunologic chaos which includes the cytokine storm. Our companion diagnostics showed that after three days of therapy, the immune profile in these patients approached normal levels and the levels of cytokines involved in the cytokine storm were much improved," Patterson said in a statement.

Jacob Lalezari, who is the interim chief medical officer at CytoDyn, noted that the preliminary results offered hope that leronlimab may help hospitalized patients with COVID-19 recover from the pulmonary inflammation that drives mortality and the need for ventilators.

"A leading medical center in the heart of the New York City epidemic was instrumental in giving the preliminary data," added Lalezari.

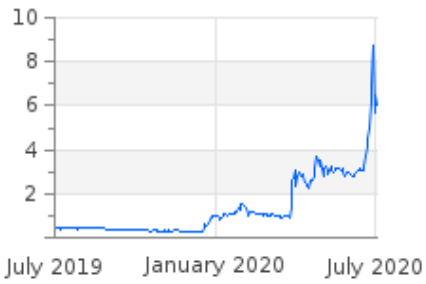
IND modifications

Meanwhile, in a separate statement, CytoDyn said it has filed another round of modifications to its IND and protocol for a Phase 2 clinical trial with leronlimab. The FDA suggested the company file a second randomized protocol for "all COVID-19 patients in severe condition," so as to preclude each physician from filing an emergency IND for every

Price: 6.08

Market Cap: $3.16 billion

1 Year Share Price Graph



Share Information

Code:	CYDY	
Listing:	OTCQB	
52 week	**High**	**Low**
	10.01	**0.261**
Sector:	**Pharma & Biotech**	
Website:	**www.cytodyn.com**	

Company Synopsis:

CytoDyn is a biotechnology company focused on the clinical development and potential commercialization of humanized monoclonal antibodies for the treatment and prevention of Human Immunodeficiency Virus (HIV) infection. The Company has one of the leading monoclonal antibodies under development for HIV infection, PRO 140, which has finished Phase 2 clinical trials with demonstrated antiviral activity in man.

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patient to be treated with leronlimab.

The first Phase 2 clinical trial that was filed on March 26 is a randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of leronlimab in patients with mild to moderate documented COVID-19 illness and calls for 75 planned patients in up to 10 centers in the US. Patients enrolled in the trial are expected to have a treatment window of approximately 6 weeks.

"On behalf of all COVID-19 patients, we are thankful for the FDA's responsiveness and their ability to provide timely guidance in order to collaboratively finalize our Phase 2 trial protocols," said CytoDyn CEO Nader Pourhassan.

"We will now also immediately file a second trial protocol, per the FDA's suggestion, for severely ill COVID-19 patients," he added.

The CytoDyn boss said he was "very hopeful" that leronlimab "can help to reduce the rate of mortality among COVID-19 patients with severe symptoms of Acute respiratory distress syndrome (ARDS)."

Aside from the coronavirus, CytoDyn is developing leronlimab to battle multiple diseases. The company has also filed an IND application and a Phase 2 clinical trial protocol with the FDA to treat patients with NASH — damage caused by a build-up of fat in the liver.

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