CytoDyn Inc.

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CytoDyn says that independent safety review of Phase 3 leronlimab trials found no concerns

CytoDyn Inc (OTCQB:CYDY) announced Tuesday that an independent safety review of its ongoing Phase 3 clinical trial of leronlimab found no concerns and recommended the trial continue.

The review was conducted by the Data Safety Monitoring Committee (DSMC), which looked at compiled safety data from 149 patients enrolled in the trial.

Leronlimab is being studied as a potential treatment for the coronavirus (COVID-19). The treatment was previously granted Fast Track designation by the US Food and Drug Administration for the treatment of HIV in combination with highly active antiretroviral therapy (HAART), and for metastatic triple-negative breast cancer, a rare variety which doesn't respond to some treatments.

READ: CytoDyn says FDA seeks more information to complete a review for leronlimab as a combination therapy for HIV patients

Vancouver, Washington-based CytoDyn has 169 enrolled patients in its Phase 3 study and will conduct a full interim analysis once 195 patients are enrolled, as provided in the trial's protocol, it said in a release Tuesday.

In a statement, CEO Nader Pourhassan thanked the DSMC for its "diligence, guidance and support.

"We are grateful to be less than 30 patients away from our planned interim analysis enrollment goal, and we look forward to sharing those interim efficacy results as soon as possible."

The Phase 3 randomized, double blind, placebo controlled, adaptive design multicenter two arm study is designed to evaluate the safety and efficacy of leronlimab in patients with severe or critical symptoms of respiratory illness caused by COVID-19. Patients are randomized 2:1 (two leronlimab: one placebo) to receive weekly doses of 700 milligrams leronlimab or placebo through subcutaneous injection.

Chief scientific officer Jacob Lalezari added that the firm "eagerly awaits" the results of the pending full interim analysis of CD12, as well as the complete safety and efficacy results from CD10, a recently completed study of patients with mild to moderate COVID-19 illness.

"We are very pleased the DSMC reported no safety concerns in CD12, a population with very severe illness and comorbidities at study entry," Lalezari said in a statement.

"We believe these results will provide compelling proof of efficacy and soon provide the world with a broadly effective therapeutic option for this devastating pandemic."

Price: 2.68

Market Cap: $1.53 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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