CytoDyn Inc.

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CytoDyn seeks UK approval for its flagship drug leronlimab for HIV and coronavirus

CytoDyn Inc (OTCQB:CYDY), which is developing leronlimab (PRO 140) to battle multiple diseases, said Friday that it will submit requests for pre-submission meetings in the UK for the drug as an HIV treatment in combination with highly active antiretroviral therapy (HAART), for highly treatment-experienced HIV patients, as a 350 mg self-injectable dose.

In addition, the Vancouver, Washington-based company said it will seek emergency approval of leronlimab for coronavirus (COVID-19) patients with mild-to-moderate symptoms.

CytoDyn said it will share its topline report from the Phase 2 trial, along with the Clinical Study Report (CSR). The company will also prepare requests for pre-submission meetings in European Union member countries.

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The company's submission to the UK government's Medicines and Healthcare Products Regulatory Agency (MHRA) will initiate the process to seek approval for leronlimab as a combination therapy for treatment-experienced HIV patients using a 350 mg weekly dose. The company's Phase 3 trial for leronlimab as a combination therapy for highly treatment-experienced HIV patients met its primary endpoint (p = 0.0032) for the trial based on a 350 mg dosage, self-injectable, once-a-week.

In a statement, CytoDyn CEO Nader Pourhassan said: "We have been working with MHRA and have provided requested information and we are hopeful that we can quickly and efficiently move forward with the process of potentially bringing leronlimab to global communities in need."

He added: "We will also pursue cancer indications in all these countries, as well as other potential indications for
leronlimab."

The Phase 2 trial to evaluate the effectiveness and safety of leronlimab in patients with mild-to-moderate symptoms caused by COVID-19 infection was completed in July 2020. Patients were randomized to receive weekly doses of 700 mg leronlimab, or placebo administered as injections. The patients receiving leronlimab experienced 64% fewer serious adverse events during the trial than patients receiving just a placebo.

CytoDyn's ongoing Phase 3 (CD12) trial of leronlimab in patients with severe to critical COVID-19 was reviewed by an independent Data Safety Monitoring Committee (DSMC), which reported finding "no cause" to modify the study. The Phase 3 study currently has 173 enrolled patients and the company will conduct a full interim analysis once 195 patients are enrolled.

Price: 2.46

Market Cap: $1.4 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.

action@proactiveinvestors.com

The US Food and Drug Administration (FDA) has granted Fast Track designation to CytoDyn as a combination therapy with HAART for HIV-infected patients, and for metastatic triple-negative breast cancer, a rare variety which doesn't respond to some treatments.

Contact the author Uttara Choudhury at uttara@proactiveinvestors.com

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Contact us +44 (0)207 989 0813 action@proactiveinvestors.com

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