CytoDyn Inc.

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CytoDyn wins IRB approval to give leronlimab to triple-negative breast cancer patients on compassionate grounds

CytoDyn Inc (OTCMKTS:CYDY) said Wednesday that it has received approval from the Institutional Review Board for its drug leronlimab to be given to patients with triple-negative breast cancer (TNBC) under compassionate use, which is also known as the expanded access program.

In a statement, the Vancouver, Washington-based late-stage biotechnology company said the program will allow TNBC patients who are not eligible under the ongoing Phase 1b/2 clinical trial to receive leronlimab (PRO 140). Under this protocol, patients with locally recurrent or metastatic triple-negative breast cancer who had progressed within six months or less on chemotherapy received leronlimab with a treatment of a physician's choice.

Significantly, the compassionate use or expanded access program is a potential pathway for patients with a life-threatening condition to gain access to an investigational medical product for treatment outside of clinical trials when no alternative therapy options are available.

READ: CytoDyn reports positive results from first patient in triple-negative breast cancer drug leronlimab trial

The IRB is an appropriately constituted group that has been designated to review and monitor biomedical research involving people in step with regulations of the US Food and Drug Administration.

However, it is important to bear in mind that investigational drugs, biologics or medical devices haven't yet been approved or cleared by the FDA.

"We are very pleased with the confidence demonstrated by the IRB to allow access to leronlimab for patients with triple-negative breast cancer. We are dedicated to advancing this therapeutic opportunity to many more patients in our ongoing trials," said CytoDyn CEO Nader Pourhassan.

CytoDyn recently reported that the first patient of a new Phase 1b/2 clinical trial for its metastatic triple-negative breast cancer (mTNBC) treatment, leronlimab, reported encouraging initial results.

The biotechnology company said circulating tumor cells in the patient's blood decreased significantly after leronlimab therapy at both two-week and five-week time points.

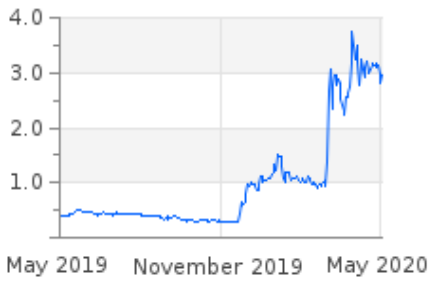
CytoDyn is developing leronlimab (PRO 140) to battle multiple diseases. Leronlimab has already completed nine clinical trials and been given to 800 patients in HIV treatment programs, Pourhassan said, without a single drug-related serious adverse event.

The drug itself works as an inhibitor of CCR5, a protein that plays a role in tumor invasion and metastasis. Blocking CCR5 has been shown to reduce tumor metastases in laboratory and animal models of aggressive breast and prostate

Price: 2.96

Market Cap: $1.43 billion

1 Year Share Price Graph



Share Information

Code:	CYDY	
Listing:	OTCQB	
52 week	**High**	**Low**
	3.84	**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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cancer.

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