CytoDyn Inc.

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CytoDyn's leronlimab sees strong positive clinical responses in two patients with metastatic breast cancer and mTNBC

CytoDyn Inc (OTCMKTS:CYDY) announced Monday continued promising clinical responses from its metastatic triple-negative breast cancer (mTNBC) Phase1b/2 trial and its trial investigating leronlimab for the treatment of metastatic breast cancer (MBC).

In a statement, the Vancouver, Washington-based late-stage biotechnology company said the first enrolled metastatic triple-negative breast cancer patient shows no detectable circulating tumor cells (CTC) or putative metastatic tumor cells in the peripheral blood and additional reductions in CCR5 expression on cancer-associated cells at 11 weeks of treatment with leronlimab.

A second patient with metastatic breast cancer has been enrolled in the trial under an emergency use investigational new drug (IND) process and additional data in the patient demonstrated shrinkage of tumor (via MRI) after three weeks of treatment with leronlimab.

READ: CytoDyn sees positive results as first triple-negative breast cancer patient treated with leronlimab

"In the first patient, we're encouraged to see that after 11 weeks these additional data provide further preliminary evidence of efficacy, as demonstrated by sustained undetectable levels of CTCs and a reduction of cancer-associated macrophage like cells (CAMLs)," said IncellDx CEO Bruce Patterson.

"Thus far, the data have been consistent with previous studies evaluating leronlimab as a long-term therapy for HIV+ patients, with no serious adverse effects reported in the mTNBC trial," he added.

CytoDyn's second patient enrolled is a stage 4 metastatic breast cancer patient. The metastasis progressed to the liver, lung and brain. This patient was enrolled through an emergency IND. The patient was on Herceptin and Perjita for over 1.5 years. Herceptin is known to stop working after about 12 months, while Perjita is effective for roughly 1.5 years. This patient received her first injection of leronlimab on November 25, with one 700 mg dose each week.

"It is very exciting to see ongoing results that demonstrate leronlimab's potential as a therapeutic option to treat patients with mTNBC and MBC with HER2+ condition. This second patient was enrolled in an emergency IND," said CytoDyn CEO Nader Pourhassan.

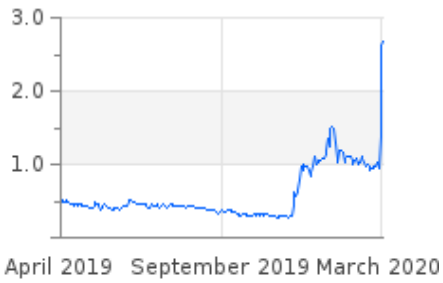
"The results from two subsequent scans of the metastatic lesions for this second patient demonstrated shrinkage of the tumors at both timepoints following the first leronlimab injection, reduction in brain edema, and remarkably, disappearance of several metastatic tumors," he added.

The CytoDyn boss said that due to the "very promising clinical data," the company feels that the 98% inhibition of

Price: 3.07

Market Cap: $1.32 billion

1 Year Share Price Graph



Share Information

Code:		CYDY
Listing:		OTCQB
52 week	**High**	**Low**
	3.5	**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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metastasis shown by animal studies may soon become a reality for many cancer patients throughout the world.

"We are cautiously optimistic and believe we have enough results in an unmet medical need population to justify filing for Breakthrough Therapy Designation in January 2020," said Pourhassan.

Leronlimab blocks CCR5, a cellular receptor, which has found to be important in HIV infection, tumor metastases, and other diseases including non-alcoholic fatty liver disease (NASH).

CytoDyn is developing leronlimab to battle multiple diseases. The company has filed an IND application and a Phase 2 clinical trial protocol with the US Food and Drug Administration for leronlimab to treat patients with non-alcoholic steatohepatitis (NASH).

Leronlimab has also already completed nine clinical trials and been given to 800 patients in HIV treatment programs, without a single drug-related serious adverse event. CytoDyn is also exploring leronlimab's use in the treatment of inflammatory conditions and autoimmune diseases.