CytoDyn Inc.

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CytoDyn sees positive data for leronlimab in Phase 1b/2 mTNBC and expanded access studies for MBC

CytoDyn Inc (OTCMKTS:CYDY), a late-stage biotechnology company, revealed continued positive data from its clinical trials evaluating its lead drug leronlimab (PRO 140) for the treatment of metastatic triple-negative breast cancer (mTNBC) and metastatic breast cancer (MBC).

In a statement, Vancouver, Washington-based CytoDyn said both types of cancer pose "significant challenges" for patients due to their "aggressiveness" and limited treatment options.

The company shared results from the first five patients:

Patient #1: The first patient enrolled in the mTNBC Phase 1b/2 trial was injected on September 27, 2019. Circulating tumor cells (CTC) dropped to zero in two weeks on October 11 last year. Total CTC and EMT (Epithelial Mesenchymal Transition in Tumor Metastasis) dropped to zero after about a month of treatment with leronlimab (once-a-week 350 mg dose). After around four months of treatment with leronlimab and carboplatin, the patient had zero CTC+EMT. Most importantly, the patient's CT scan indicated a 20% tumor shrinkage within the first few weeks of treatment with leronlimab.

READ: CytoDyn's impressive run continues for leronlimab in metastatic triple-negative breast cancer and metastatic breast cancer

Patient #2: The second patient was enrolled through an emergency investigational new drug (IND) process with metastatic stage four breast cancer that had metastasized to the liver, lung and brain. The patient's radiologist cancelled the second round of treatment due to leronlimab's effect on shrinking the largest tumor in the brain by 56% and other lesions being stable. Leronlimab has, and continues to be, the only treatment in place since the measurement of brain tumor shrinkage was initiated. Patient was permitted to obtain CTC+EMT test results. After 10 weeks of treatment with leronlimab, the patient's CTC+EMT results were zero, according to results reported on February 2 this year.

Patient #3: The third patient was enrolled on January 3. The patient's CAML counts went down from 45 to 30. CTC+EMT are stable and there has been no change in the total number, said the company.

Patient #4: The fourth patient was enrolled on January 7 and the patient's total CTC+EMT dropped by 75% in the first two weeks of treatment with leronlimab.

Patient #5: The fifth patient was enrolled on February 4 and the patient's CTC+EMT have been recorded and the first results are expected on February 25.

In addition to the first five patients, enrollment and treatment updates in CytoDyn's Phase 2 protocol basket trial under its cancer IND are as follows:

Price: 2.98

Market Cap: $1.44 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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- Patient #6: Was injected on February 8 and the first results since enrollment are due by end-February;
- Patient #7: Was injected on February 13; and
- Patients #8, 9 and 10: Have completed screening for enrollment.

"The patients enrolled in the mTNBC Phase 1b/2 trial continue to demonstrate meaningful results that support the hypothesis regarding leronlimab's mechanism of action," said IncellDx founder CEO Bruce Patterson, who is both a diagnostic partner and advisor to CytoDyn.

"In the four patients (1 with MBC, 3 with TNBC) now with results from leronlimab therapy, patients #1-3 have zero CTCs and zero EMTs and Patient #4, who has been treated with leronlimab for 2 weeks showed a decrease of CTCs and EMTs from 8 to 2. New data from Patient #2 with Stage 4 MBC and who has been treated with 10 weekly doses of leronlimab showed zero CTCs and zero EMTs, in addition to the shrinkage or disappearance of some brain metastases as previously reported," he added.

Meanwhile, CytoDyn CEO Nader Pourhassan, said the findings are "extremely promising" in light of the success rate of other treatment options.

Filing for Breakthrough Therapy status for all solid tumor cancers

"Therapeutic options for patients suffering from breast cancer are highly limited and we look forward to continuing enrollment and exploring leronlimab's potential to treat this devastating disease," Dr Pourhassan.

"Since our basket trial for all solid tumor cancers has been initiated, we are currently screening a prostate cancer patient, and if continued positive clinical results are forthcoming from this patient, we are hopeful that this will clear the path for CytoDyn to file for Breakthrough Therapy designation for all solid tumor cancers."

Dr Pourhassan noted that leronlimab's mechanism of action not only focused on the inhibition of metastasis of solid tumor cancers, but also "targets the tumor itself through macrophages, angiogenesis and T-reg."

CytoDyn, based in Vancouver, Washington, 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 (FDA) for leronlimab to treat patients with 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.

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