December 8, 2025

CytoDyn to Showcase PD-L1 Upregulation and Improved Survival in Metastatic Triple Negative Breast Cancer at the San Antonio Breast Cancer Symposium

Leronlimab treatment is associated with upregulation of PD-L1 in circulating tumor cells and cancer-associated macrophage-like cells

Remarkably longer survival was observed in patients treated with leronlimab in combination with or followed by an immune checkpoint inhibitor

VANCOUVER, Washington, Dec. 08, 2025 (GLOBE NEWSWIRE) -- **CytoDyn Inc. (OTCQB: CYDY)** ("CytoDyn" or the "Company"), a clinical-stage oncology company advancing leronlimab, a first-in-class humanized monoclonal antibody targeting the CCR5 receptor with therapeutic potential across multiple indications, including metastatic triple-negative breast cancer ("mTNBC") and colorectal cancer ("mCRC"), today announced that breast cancer specialist and medical oncologist, Milana V. Dolezal, MD, MSci, is presenting a poster entitled "*Prolonged survival following PD-L1/PD-1 immune checkpoint inhibitor therapyafter leronlimab induced PD-L1 upregulation on cancer-associated macrophage-like cells and circulating tumor cells in patients with metastatic or locally advanced triple-negative breast cancer*" at the San Antonio Breast Cancer Symposium (SABCS). The poster (ID: PS5-02-30) will be presented in the Exhibit Hall on December 12, 2025, from 12:30 p.m. – 2 p.m. CST.

"These leronlimab early-phase clinical trials were started pre-pandemic, when immune checkpoint inhibitors ("ICIs") were still an emerging option in advanced triple-negative breast cancer," said Dr. Milana V. Dolezal. "In this pooled analysis, we see sustained clinical benefit over five years later, with five participants (17.9%) still alive and disease-free after treatment with leronlimab, either concurrently with or prior to an ICI. The alignment of these outcomes with emerging mechanistic data, showing leronlimab-driven PD-L1 upregulation, suggests potential synergy with ICIs. This is very encouraging and supports further prospective evaluation. The observed PD-L1 upregulation in the tumor microenvironment, including circulating cells, could have broad oncology implications, including expanding eligibility for ICI combination therapies. In addition, weekly leronlimab injections are well tolerated, with few treatment-emergent adverse events."

The poster presents updated results from a retrospective follow-up analysis of data from 28 women with mTNBC, who were treated across three leronlimab clinical trials and received a median of 2 prior lines of therapy in the metastatic setting. No dose-limiting toxicities (DLTs) were observed, and no patients withdrew due to treatment-related adverse events.

Key Findings:

- 100% of patients (n=5/5) who demonstrated induction of PD-L1 greater than 400

Relative Fluorescence Units ("RFUs") on circulating tumor cells (CTCs), and were then treated with an immune checkpoint inhibitor ("ICI"), remain alive after a median of 60.9 months. Three of these patients currently have no evidence of disease.

- Median Overall Survival after starting leronlimab was 7.1 months (95% CI: 4.8–17.7 months) with survival at years 1, 2, 3, and 4 of 35.7%, 21.4%, 17.9% and 17.9%, respectively.

- Patients treated with either the 525 or 700 mg dose of leronlimab demonstrated significantly longer survival (HR 3.44, 95% CI: 1.2–9.9; P=0.0418) compared to patients treated with the 350 mg dose.

- Utilizing a >400 RFU threshold, treatment with leronlimab was associated with the upregulation of PD-L1 in CTCs and cancer-associated macrophage-like cells (CAMLs) in 76% (n=16/21) of patients overall, and 88% (n=15/17) of patients who received leronlimab at a dose of 525 mg or 700 mg.

- Seven patients treated with leronlimab in combination with or followed by an ICI demonstrated significantly longer survival compared to patients (N=21) who were not treated with an ICI (HR 4.14, 95% CI: 1.7–10.2; P=0.0041).

"Given the reduced effectiveness of immunotherapy in patients with mTNBC and low PD-L1 expression, the demonstrated ability of leronlimab to upregulate PD-L1 on CTCs could be a crucial factor for enhancing the efficacy of a combined treatment approach of leronlimab with ICIs," said Jacob Lalezari, M.D., CEO of CytoDyn. "These results indicate that blocking CCR5 with leronlimab may impact tumors and the tumor microenvironment in such a way as to prime these cells to respond to immune checkpoint inhibition. Prospectively confirming these observations is our top priority."

A copy of the presentation will be made available on CytoDyn's website under the Publications & Posters section after it is presented at the symposium.

About CytoDyn
CytoDyn is a clinical-stage oncology company dedicated to advancing leronlimab, a first-in-class humanized monoclonal antibody that targets the CCR5 receptor, a key regulator of immune function implicated in cancer, infectious diseases, and autoimmune disorders. Guided by a mission to improve patients' quality of life through therapeutic innovation, CytoDyn is committed to integrity, responsibility, and service as it works to bring transformative treatments to patients worldwide.

For more information, please visit www.cytodyn.com and follow us on LinkedIn.

Note Regarding Forward-Looking Statements
This news release may contain forward-looking statements relating to, among other things, the mechanism of action of leronlimab, clinical trial results, product development, market position, future operating and financial performance, and business strategy. The reader is cautioned not to rely on these statements, which are based on current expectations of future

events. For important information about these statements and our Company, including the risks, uncertainties and other factors that could cause actual results to vary materially from the assumptions, expectations and projections expressed in any forward-looking statements, the reader should review our Annual Report on Form 10-K for the fiscal year ended May 31, 2025, including the section captioned “Forward-Looking Statements” and in Item 1A, as well as subsequent reports filed with the Securities and Exchange Commission. CytoDyn Inc. does not undertake to update any forward-looking statement as a result of new information or future events or developments except as required by applicable law.

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