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CytoDyn Announces Data Suggesting Novel Mechanism of Action of Leronlimab for the Treatment of Solid Tumors

Survival observations in mTNBC patients correlated with increased PD-L1 expression

Preliminary evidence suggests leronlimab has potential to turn “cold” tumors “hot”

VANCOUVER, Washington, May 13, 2025 (GLOBE NEWSWIRE) -- **CytoDyn Inc. (OTCQB: CYDY)** ("CytoDyn" or the "Company"), a biotechnology company developing leronlimab, a CCR5 antagonist with the potential for multiple therapeutic indications, today announced new data suggesting a novel mechanism of action of leronlimab for the treatment of solid tumors.

CytoDyn analyzed data from its prior clinical trials of patients with metastatic Triple-Negative Breast Cancer (“mTNBC”) and found that leronlimab treatment correlated with increased expression of an immune cell protein or “checkpoint inhibitor” known as programmed death-ligand 1 (“PD-L1”) on patient’s circulating tumor cells (“CTCs”). CytoDyn’s results indicate that 15/17 (88%) of patients who received a weekly dose of 525 mg or higher experienced a significant increase in PD-L1 expression on their CTCs over a 30-to-90-day period after starting leronlimab. Increasing expression of PD-L1 can be likened to turning “cold” tumors “hot”, elevating PD-L1 levels to the level necessary for patients to potentially derive benefit from further treatment with a class of drugs known as immune checkpoint inhibitors (“ICIs”).

As previously announced, CytoDyn identified a group of patients with mTNBC who had failed a median of two prior lines of treatment in the metastatic setting but showed improved overall survival rates after receiving leronlimab. The Company confirmed that 5/5 patients (100%) who demonstrated a significant increase in PD-L1 expression after receiving leronlimab *and* received treatment with any ICI remain alive today. Four of these patients (80%) currently identify as having no evidence of disease, and the fifth patient is alive and identified by the clinical site as “stable.”

If the results above are confirmed prospectively, the Company believes the mechanism could be effective across a wide range of solid tumor types, and in particular benefit cancer patients with low levels of PD-L1 who were previously unresponsive to or ineligible for checkpoint inhibitors.

“Leronlimab’s induction of PD-L1 on CTCs in patients with otherwise “cold” tumors opens a promising field of exploration for what could amount to significant improvements to patient care and outcomes in solid tumor oncology,” said Richard Pestell, MD, PhD, AO, the Company’s Lead Consultant in Preclinical and Clinical Oncology. “We are hopeful that further short-term investigation will confirm our working theory and open new pathways for patients with a range of common and aggressive forms of cancer to access treatment options that were previously out of reach.”

“We are thrilled to announce this apparent mechanism behind the improved survival in patients with refractory and metastatic TNBC,” said Dr. Jacob Lalezari, CEO of CytoDyn. “Leronlimab’s ability to induce an inflamed or “hot” tumor environment, that could then be treated with ICIs, would be a game changer in solid tumor oncology. Prospectively confirming these findings in patients with TNBC is a top priority. We have also amended our current colorectal cancer trial to ensure the prospective collection of PD-L1 data in a second type of solid tumor.”

About CytoDyn

CytoDyn is a clinical-stage biotechnology company focused on the development and commercialization of leronlimab, an investigational humanized IgG4 monoclonal antibody (mAb) that is designed to bind to C-C chemokine receptor type 5 (CCR5), a protein on the surface of certain immune system cells that is believed to play a role in numerous disease processes. CytoDyn has studied leronlimab in multiple therapeutic areas, including oncology, infectious disease, and autoimmune conditions.

Note Regarding Forward-Looking Statements

This news release contains forward-looking statements relating to, among other things, 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, 2024, including the section captioned “Forward-Looking Statements” and in Item 1A, and in 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.

Media Contacts

CytoDyn Inc.
Riyaz Lalani
Gagnier Communications
CytoDyn@gagnierfc.com

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