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CytoDyn and QLHC Advance Leronlimab into Two New PRE-I-SPY Studies in Metastatic Triple-Negative Breast Cancer

VANCOUVER, Washington, Nov. 10, 2026 (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 colorectal cancer (CRC) and metastatic triple-negative breast cancer (mTNBC), today announced that leronlimab will be evaluated in two new mTNBC regimens within the Quantum Leap Healthcare Collaborative's (QLHC) PRE-I-SPY Phase 1-1b platform study, with enrollment expected to begin shortly.

The two studies will evaluate leronlimab in distinct immunotherapy-based combinations, each incorporating a PD-1 inhibitor. PRE5 will evaluate leronlimab alongside Merck's pembrolizumab and the antibody-drug conjugate sacituzumab, while PRE7 will evaluate leronlimab in combination with Akeso's penpulimab and the standard chemotherapy agents gemcitabine and carboplatin. Both studies are designed to assess safety and tolerability in earlier-line metastatic treatment settings while exploring preliminary signals of clinical activity.

“These studies represent an important opportunity to further investigate the potential of CCR5 inhibition as part of combination treatment strategies for patients with metastatic triple-negative breast cancer,” said Jacob Lalezari, M.D., Head of Research and Translational Sciences at CytoDyn. “By evaluating leronlimab alongside different immunotherapy-based regimens and incorporating exploratory biomarker analyses, we hope to gain a better understanding of its potential role in modulating the tumor microenvironment and informing future treatment approaches for patients with this aggressive disease.”

mTNBC is an aggressive form of breast cancer characterized by the absence of estrogen receptor, progesterone receptor, and HER2 expression, limiting the applicability of several targeted treatment approaches used in other breast cancer subtypes. The two Phase 1 studies will evaluate leronlimab in combination with established treatment regimens and will incorporate exploratory biomarker assessments, including circulating tumor DNA (ctDNA) and PD-L1 expression, to generate early insights that may help inform subsequent clinical development.

“There remains a need to better understand how novel combination strategies can improve treatment for patients with metastatic triple-negative breast cancer,” said Paula Pohlmann, M.D., Ph.D., of The University of Texas MD Anderson Cancer Center and principal investigator for both studies. “PRE-I-SPY allows us to evaluate safety while simultaneously examining biological markers that may provide an early indication of how these treatment combinations are affecting the disease.”

PRE-I-SPY Study Design and Patient Populations

Both studies will primarily evaluate the safety and tolerability of leronlimab-containing combinations while assessing preliminary signals of clinical activity and exploratory biomarkers, including ctDNA and PD-L1 expression as measured by combined positive score (CPS).

PRE5 will primarily enroll patients receiving first- or second-line treatment, while PRE7 will focus on patients receiving second-line treatment. Both studies will include patients with a CPS of less than 10.

Both study arms will use a de-escalation design that starts at the highest dose of leronlimab (700mg) and evaluates dose reductions based on a one-cycle, 21-day dose-limiting toxicity (DLT) observation period. Cohorts will include six patients each and are designed to potentially expand if no DLTs are observed in the first cohort.

PRE-I-SPY is a Phase 1 platform study designed to efficiently evaluate the safety and optimal dosing of new therapeutic agents and combinations for breast cancer. QLHC is the sponsor of the PRE-I-SPY platform study, while CytoDyn is providing leronlimab for evaluation in the two new regimens.

“An important goal of PRE-I-SPY is to identify promising therapeutic combinations with acceptable safety profiles that could potentially be evaluated in earlier-stage, high-risk breast cancer through the I-SPY 2.2 platform,” said Laura Esserman, M.D., Co-founder of QLHC and Principal Investigator of the I-SPY 2 platform.

Preparations are already underway for both studies, and enrollment for PRE5 is expected to begin in the first quarter of calendar 2027. Enrollment for PRE7 is likely to begin in the second or third quarter of calendar 2027. Additional information and updates on both studies will be provided in future Company communications.

About Quantum Leap Healthcare Collaborative

Quantum Leap Healthcare Collaborative (QLHC) is a 501c(3). It is a nonprofit pioneer that designs, implements, and succeeds at building and iterating creative and nimble solutions that drive meaningful results for patients. QLHC’s mission is to better serve patients by accelerating and innovating health care through approaches that challenge the status quo of science and care. QLHC’s efforts focus on achieving our long-term vision to improve human health for all through personalized medicine by bridging the gap between research and care. QLHC provides operational, financial, and regulatory oversight to I-SPY.

For more information, visit https://www.quantumleaphealth.org/.

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, mechanism of action, clinical development programs, 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, 2026, 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.

Corporate Contact
CytoDyn Inc.
ir@cytodyn.com

Media Contacts
David Schull or Ignacio Guerrero-Ros, Ph.D.
Russo Partners, LLC
CytoDyn@russopartnersllc.com

Source: CytoDyn Inc.