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CytoDyn Completes Enrollment in Phase 2 Metastatic Colorectal Cancer Study

Enrollment concludes with just over 60 patients participating across seven clinical sites located throughout the United States

VANCOUVER, Washington, April 21, 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 metastatic triple-negative breast cancer (“mTNBC”) and colorectal cancer (“mCRC”),” today announced the completion of enrollment in its Phase 2 clinical study (ClinicalTrials.gov Identifier: NCT06699836) evaluating leronlimab in combination with trifluridine and tipiracil (TAS-102) plus bevacizumab in patients with CCR5-positive, microsatellite stable (MSS), relapsed/refractory metastatic colorectal cancer (mCRC), also known as CLOVER – **C**CR5-targeting **L**eronlimab With **O**ral Chemotherapy and **V**EGF-inhibitor **E**nriched **R**egimen.

The open-label, randomized, two-arm, multi-center study is evaluating leronlimab in combination with trifluridine and tipiracil (TAS-102) plus bevacizumab in patients who have progressed following prior standard therapies. With enrollment now complete, CytoDyn will advance the study through treatment and follow-up, with resulting data expected to inform the program’s development strategy and potential next steps.

“Completing enrollment in this Phase 2 study marks an important milestone for CytoDyn and for the continued development of leronlimab in oncology,” said Dr. Jacob Lalezari, Chief Executive Officer of CytoDyn. “We are grateful to the patients, investigators, and clinical sites whose commitment made completion of enrollment possible and look forward to evaluating the study results.”

“CLOVER is designed to prospectively assess the activity of leronlimab in combination with an established regimen in a difficult to treat and highly refractory patient population with microsatellite stable (MSS) metastatic colorectal cancer, ” said Pashtoon M. Kasi, M.D., M.S., Principal Investigator of the study and Medical Director of GI Oncology, City of Hope Orange County, Irvine, California. “With enrollment now complete, the study is well positioned to generate meaningful insights in this patient population with a high unmet need.”

The CLOVER study builds on emerging clinical and translational findings from CytoDyn’s ongoing Phase 2 mCRC program, including data being presented at the AACR Annual Meeting 2026. Preliminary results demonstrated early signals of clinical and biomarker activity with leronlimab in combination with TAS-102 and bevacizumab, including rapid reductions in circulating tumor DNA and modulation of immune-related markers. These findings support further evaluation of CCR5 inhibition as a strategy to enhance anti-tumor activity in metastatic colorectal cancer.

Leronlimab is a monoclonal antibody targeting CCR5, a receptor involved in immune cell trafficking and tumor biology. By blocking CCR5, leronlimab may help modulate the tumor microenvironment and enhance the activity of existing therapies in difficult-to-treat cancers.

CytoDyn plans to share topline data from the study as they become available.

About the Phase 2 mCRC Study (NCT06699836)
This Phase 2 clinical study is an open-label, randomized, two-arm, multi-center study evaluating leronlimab in combination with trifluridine and tipiracil (TAS-102) plus bevacizumab in patients with CCR5-positive, microsatellite stable (MSS), relapsed/refractory metastatic colorectal cancer (mCRC), also known as CLOVER – **C**CR5-targeting **L**eronlimab With **O**ral Chemotherapy and **V**EGF-inhibitor **E**nriched **R**egimen.

Approximately 60 patients were enrolled and randomized 1:1 to receive either 350 mg or 700 mg of leronlimab in combination with standard-of-care therapy. Eligible participants are adults with histologically confirmed mCRC who have progressed following prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, anti-VEGF therapy, and, where appropriate, anti-EGFR therapy.

The primary endpoint of the study is objective response rate (ORR), as defined by RECIST v1.1 criteria. Secondary endpoints include safety and tolerability, duration of response, and overall survival. Patients will be followed for up to 12 months.

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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