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CytoDyn Presents Updated Leronlimab Data in Metastatic Colorectal Cancer at ESMO Congress 2026

- Phase 2 CLOVER study enrolled 66 patients across seven sites in metastatic colorectal cancer
- Updated data show universal CCR5 expression, early ctDNA reductions and favorable tolerability

VANCOUVER, Washington, Oct. 26, 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 (mCRC) and metastatic triple-negative breast cancer (mTNBC), today announced that updated clinical and translational data from its ongoing Phase 2 CLOVER study (ClinicalTrials.gov Identifier: NCT06699836) evaluating leronlimab in combination with trifluridine and tipiracil (TFD/TPI) plus bevacizumab in mCRC were presented at the ESMO Congress 2026, held October 23–27, 2026, in Madrid, Spain.

The poster presentation, titled "*Leronlimab (LRM) in combination with trifluridine/tipiracil (TAS-102) plus bevacizumab (BEV) in metastatic colorectal cancer (mCRC): The phase 2 CLOVER study*," was presented by Benjamin Weinberg, M.D., Associate Professor at Georgetown University on Sunday, October 25, 2026, from 4:00 – 4:45 a.m. PDT (12:00 - 12:45 p.m. CET), as Poster #820P, and included updated safety and biomarker findings from the multicenter study in patients with previously treated mCRC.

CCR5 is implicated in the recruitment of immunosuppressive immune cell populations, including regulatory T cells and myeloid cells, into the tumor microenvironment and may contribute to immune evasion in colorectal cancer. The CLOVER study is evaluating the safety of adding leronlimab to TFD/TPI plus bevacizumab and whether CCR5 inhibition may enhance anti-tumor activity through immune modulation. The study's primary efficacy endpoint is objective response rate ("ORR"), defined as the proportion of patients achieving a confirmed complete or partial response according to RECIST v1.1.

"These updated findings continue to provide important insight into the biological effects of CCR5 inhibition in metastatic colorectal cancer, particularly through the integration of tissue and blood-based biomarkers," said Benjamin Weinberg, M.D., Associate Professor of Medicine at Georgetown University. "The consistent CCR5 expression observed across all evaluable tumor samples, together with rapid, early reductions in circulating tumor DNA, supports continued investigation of leronlimab in combination with established therapies for patients with refractory disease."

Key findings from the Phase 2 CLOVER study include:

- **66 patients were enrolled across seven clinical sites** between June 2025 and May 2026. Leronlimab was administered subcutaneously once weekly at either 350 mg or 700 mg in combination with standard doses of TFD/TPI and bevacizumab.
- **CCR5 expression was detected in 100% of evaluable archival tumor samples (91/91)** from pre-screened patients, further supporting investigation of CCR5 as a potential therapeutic target in mCRC.
- **In 28 patients with available baseline** and Week 2 ctDNA results, a **median reduction of 86% in ctDNA was observed at Week 2**.
- Among the 32 patients with currently available safety data, **no leronlimab-related adverse events led to treatment discontinuation and no leronlimab-related adverse events greater than Grade 2 were reported**. No leronlimab-related dose-limiting toxicities were observed.
- **The TFD/TPI + bevacizumab + leronlimab combination demonstrated deeper ctDNA responses**, with significantly greater reductions in molecular residual disease (MRD) from baseline versus TFD/TPI + bevacizumab at both 0–4 weeks (**p=0.0005**) and 0–8 weeks (**p=0.0006**), as well as deeper MRD reductions than TFD/TPI alone at both time points.

“We are encouraged by the consistent CCR5 expression across evaluable tumor samples and the early ctDNA reductions observed in patients with available data,” said Jacob P. Lalezari, M.D., Head of Research and Translational Sciences at CytoDyn. “These findings give us additional insight into how leronlimab may be interacting with the biology of metastatic colorectal cancer while maintaining a favorable tolerability profile in combination with TFD/TPI and bevacizumab. The expanded biomarker data being presented at ESMO will help further characterize these observations and inform the continued development of this program.”

A copy of the poster will be made available on CytoDyn’s website under the Publications & Posters section.

About the European Society for Medical Oncology (ESMO) Congress 2026
The ESMO Congress 2026, taking place October 23–27, 2026, in Madrid, Spain, is a leading global oncology meeting bringing together clinicians, researchers, patient advocates, journalists and healthcare industry representatives from around the world. The Congress provides a global platform for advances in oncology research, clinical practice and patient care, featuring new scientific data, educational programming, networking opportunities and innovation across the oncology community. For more information, visit esmo.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, 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, 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.

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