

CytoDyn Announces First Patient Dosed in Phase II Oncology Trial in Colorectal Cancer

Enrollment is now underway across multiple clinical sites, in partnership with Syneos Health

VANCOUVER, Washington, June 24, 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 that the first patient has been dosed in the Company's clinical trial evaluating the efficacy of leronlimab in patients with relapsed/refractory microsatellite stable colorectal cancer ("CRC").

In partnership with Syneos Health, the Company has engaged eight clinical sites and counting, and patient enrollment and processing efforts are underway. The lead principal investigator for the trial is Dr. Ben Weinberg, MD, from Georgetown University and the MedStar Health Alliance.

According to the World Health Organization's International Agency for Research on Cancer ("IARC"), colorectal cancer is the third most common cancer type worldwide, and the second most common cause of cancer-related deaths globally. IARC's most recently published figures estimate that there are about 1.9 million new cases of colorectal cancer and more than 900,000 deaths due to colorectal cancer worldwide each year. The IARC also noted that the incidence rates of colorectal cancer in people younger than 50 years old have been increasing for at least 20 years, with some sources dating the increase trend back 30 years or more.

"Dosing the first patient in our Phase II CRC trial is a significant step forward in our mission to bring innovative treatment options to patients facing this challenging disease. This milestone reflects the dedication of our team and clinical partners, and we look forward to advancing this study to better understand the potential impact of our therapy across solid tumor oncology," said Dr. Jacob Lalezari, CEO of CytoDyn.

The study builds on the Company's prior research demonstrating the potential clinical benefit of leronlimab in patients with relapsed CRC, and will also further the evaluation of the potential for the Company's <u>recently announced mechanism of action for leronlimab in solid tumor oncology</u>. Given the promising survival rates observed in the Company's prior studies in patients with metastatic triple-negative breast cancer and the Company's ongoing clinical investigation efforts in CRC, CytoDyn views its current line of scientific evaluation as the most expeditious path to determining how broadly applicable this mechanism may prove to be across various solid tumors.

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.

About Syneos Health

Syneos Health® is a leading fully integrated biopharmaceutical solutions organization built to accelerate customer success. Syneos Health translates unique clinical, medical affairs and commercial insights into outcomes to address modern market realities. Syneos Health brings a talented team of professionals with a deep understanding of patient and physician behaviors and market dynamics. Together, Syneos Health shares insights, uses the latest technologies and applies advanced business practices to speed its customers' delivery of important therapies to patients. Syneos Health supports a diverse, equitable and inclusive culture that cares for colleagues, customers, patients, communities and the environment. To learn more about how Syneos Health is shortening the distance from lab to life®, visit syneoshealth.com.

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