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CytoDyn Announces Encouraging Survival Data in Patients with Metastatic Colorectal Cancer Previously Treated with Leronlimab

Positive results in patients with advanced mCRC emphasize potential significance of CytoDyn's ongoing Phase II CRC trial

Dr. Benjamin Weinberg to present final results at the ESMO Gastrointestinal Cancers Congress 2025 in Barcelona, Spain

VANCOUVER, Washington, July 01, 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 encouraging clinical findings among patients with advanced metastatic colorectal cancer ("mCRC") previously treated with leronlimab. The final results indicate that 3/5 patients treated with leronlimab had at least a partial response, as measured by radiologic criteria, including one patient with a complete response who remains alive five years later.

Dr. Benjamin Weinberg, Associate Professor at Georgetown University and Principal Investigator of CytoDyn's colorectal cancer ("CRC") program, will present the Company's clinical data at the ESMO Gastrointestinal Cancers Congress 2025 taking place in Barcelona, Spain from July 2 to July 5, 2025.

The results, from patients treated under a compassionate use protocol, reiterate a favorable safety profile of leronlimab as well as its potential for clinical benefit in patients with mCRC. They also support the rationale for the design and therapeutic potential of CytoDyn's ongoing Phase II trial in patients with relapsed/refractory microsatellite stable CRC. CytoDyn [recently announced the dosing of the first patient](#) in this study, and is now enrolling additional patients across multiple clinical sites.

If the observed results in the previously treated CRC patients are confirmed prospectively, the Company believes leronlimab could be used effectively to treat a wide range of solid tumor types. In addition to its potential as a "stand-alone" agent in oncology, the Company presented exciting evidence of leronlimab's activity as a "priming" agent for cancer patients with low levels of PD-L1 who were previously unresponsive to, or ineligible for, checkpoint inhibitors at the 2025 ESMO Breast Cancer meeting. The data driving this working theory has shown particular promise in the treatment of patients with advanced metastatic triple-negative breast cancer ("mTNBC").

"At the 2025 ESMO Gastrointestinal Cancers Congress, Dr. Weinberg will share the data

and evidence that form the basis for our belief in the potential of leronlimab as a treatment in CCR5 positive solid tumor oncology,” said Dr. Jacob Lalezari, CEO of CytoDyn. “Our ongoing Phase II trial in patients with mCRC was designed to prospectively confirm these observations, and we look forward to enrolling additional patients as we pursue clinical confirmation of our working theory.”

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.

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