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CytoDyn Announces Findings of Statistically Significant Fibrosis Reversal Across Studies with SMC Laboratories

VANCOUVER, Washington, Feb. 06, 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, announced today positive results from its preclinical studies with SMC Laboratories (“SMC”).

The three studies demonstrated statistically significant reversal of liver fibrosis with leronlimab monotherapy (compared to an isotype IgG4 control arm with p-values across all 3 studies < 0.01). The first two studies, completed in late 2024, evaluated leronlimab in the STAM™ model of metabolic dysfunction associated steatohepatitis (MASH) with fibrosis in mice who received a single dose of Streptozocin at birth and were then fed a high fat diet from weeks four to twelve. The third study, concluded in January 2025, evaluated reversal of liver fibrosis in mice who received carbon tetrachloride, a liver fibrosis-inducing agent, from birth to sacrifice at day 35.

“The management of patients with advanced liver fibrosis due to a variety of etiologies is an area of enormous unmet need in the field of hepatology. The results of these three preclinical studies support both the biologic activity and potential clinical benefit of leronlimab’s ability to bind to CCR5 receptors on hepatic stellate cells, leading to a reversal of established liver fibrosis,” said Melissa Palmer, MD FAASLD, the Company’s Lead Consultant in Hepatology.

Dr. Jacob Lalezari, CEO of CytoDyn, added, “We are very encouraged by these initial findings, which add to the growing body of evidence that leronlimab’s core mechanism of action, binding to CCR5 receptors on cells, could translate into a variety of meaningful clinical benefits for patients across a number of medical conditions. As the Company continues to prioritize its oncology objectives for 2025, we look forward to establishing the right partnership to further the clinical development pathway for leronlimab in the treatment of fibrosis of the liver and potentially other organs, such as the lungs and heart.”

CytoDyn is currently in discussions with several third parties regarding next steps in an effort to expand on these promising findings. The Company intends to explore a number of potential synergies and partnership opportunities in the coming months as it furthers its clinical development pipeline, including opportunities that might explore the potential widespread applications for leronlimab as a treatment path for fibrosis in other organs.

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 infectious disease, oncology, and autoimmune conditions.

About SMC Laboratories

SMC Laboratories, Inc. is a CRO, with a focus on conducting the non-clinical research necessary for the drug development process. As a global consulting company that designs studies according to customer requests, it supports cutting-edge non-clinical pharmacological studies. The company owns a variety of mouse models for inflammation and fibrosis in various organs, centered on the innovative STAM™ mouse animal model of liver cancer derived from MASLD (metabolic dysfunction-associated steatotic liver disease). This patented mouse model was developed by SMC Laboratories as a worldwide-first model based on MASLD. We offer non-clinical pharmacological studies using the model mouse. Please check the company's website for further details.

Note Regarding Forward-Looking Statements

This news release contains forward-looking statements relating to, among other things, 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. 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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