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CytoDyn Announces Preliminary Findings in Study with SMC Laboratories

VANCOUVER, Washington, Sept. 24, 2024 (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 a preliminary review of results from its preclinical study with SMC Laboratories.

SMC Laboratories, a company specializing in preclinical drug efficacy evaluations using various models of inflammation and fibrosis in mice, conducted a study that assessed the optimal dosing of leronlimab in the MASH setting and potential synergies with Resmetirom, the only currently approved therapy for the treatment of MASH. A preliminary review of the study results has led to several encouraging findings, as follows:

i. Leronlimab monotherapy (700 mg) demonstrated statistically significant fibrosis reversal compared to an isotype IgG4 control arm ($p<0.01$);

ii. Leronlimab monotherapy appeared to demonstrate dose-dependent antifibrotic activity, with leronlimab 700 mg performing better at reversing liver fibrosis compared to leronlimab 350 mg; and

iii. Leronlimab monotherapy (700 mg) appears to have better anti-fibrotic activity compared to Resmetirom ($p=0.057$).

“These initial results are very exciting and confirm our belief that leronlimab has the potential to be materially beneficial for patients suffering from a number of medical concerns,” said Dr. Jacob Lalezari, CEO of CytoDyn. “While additional research is necessary to confirm and explore these findings further, we are very encouraged about the potential for leronlimab to support therapeutics meant to address MASH and specifically fibrosis and related complications in the liver.”

CytoDyn is in discussions with SMC Laboratories regarding next steps – including supplemental lab studies to expand on these promising findings, further explore potential synergies and continue to advance the Company’s clinical pipeline.

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.

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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