November 4, 2024

CytoDyn Announces FDA Clearance of Its Phase II Oncology Trial

VANCOUVER, Washington, Nov. 04, 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 that it has received clearance from the FDA to commence its Phase II oncology trial. The study will evaluate the efficacy of leronlimab in patients with relapsed/refractory microsatellite stable colorectal cancer (“CRC”).

This milestone reflects the continued positive development of the Company’s improved relationship with the FDA. Clearance for the Phase II oncology trial was achieved following productive feedback sessions with the FDA over the past few months and the submission of a final study protocol to the FDA in September 2024. As previously announced, the trial will be conducted in partnership with Syneos Health. A trial kickoff meeting has been set for late November 2024 and patient enrollment will begin in early 2025.

“We have appreciated the opportunity to work constructively with the FDA on the review and finalization of our CRC protocol,” said Dr. Jacob Lalezari CEO. “With the agency’s input and our partnership with Syneos Health, we are well positioned to advance our clinical evaluation of leronlimab for oncology and make real strides towards developing the treatment paths of tomorrow.”

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. Leronlimab is being studied for oncology and inflammation, as well as other potential indications, including but not limited to HIV and MASH.

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.

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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