September 9, 2024

September 2024 Letter to Shareholders

VANCOUVER, Washington, Sept. 09, 2024 (GLOBE NEWSWIRE) --

Dear Shareholders,

It continues to be a transformative year for CytoDyn Inc. (“CytoDyn” or the “Company”). A year in which we have made significant strides as a company, pursuing strategic initiatives to further our clinical development pipeline and charting the path forward in support of our mission. I sincerely thank you for your continued support and remain excited for what lies ahead.

As we enter the final stretch of 2024, let me first acknowledge that there is still a great deal of work ahead of us. The board of directors and the management team of the Company remain focused on advancing our clinical pipeline and opportunities to drive value for shareholders.

We are committed to being transparent with our shareholders and it is my pleasure to provide an update on some key developments described below.

CytoDyn has accomplished a number of milestones since the FDA lifted the clinical hold on leronlimab in March 2024, including: (i) the submission of two clinical trial protocols to the FDA, (ii) the negotiation of various agreements with vendors and creditors, and (iii) the settlement of litigation with Amarex resulting in an immediate $10 million cash influx into the Company, with an additional $2 million to be received in 2025. These important developments were necessary steps to prepare the way for CytoDyn to launch pivotal studies to address the potential role of leronlimab in the clinic.

As of today, the Company has a new and improved relationship with the FDA – one that will remain a critical priority for the management team in the coming years. We believe the Company has sufficient cash on hand to commence the contemplated clinical trials and push our development initiatives forward into 2025.

CytoDyn has made significant progress by initiating a variety of key pre-clinical and clinical leronlimab trials, to be funded by the Company and others. I am also pleased to share that we have observed considerable progress related to development of a longer-acting therapeutic with our partner, who utilizes a proprietary artificial intelligence platform to expedite the clinical development process.

As shareholders, you remain the lifeblood of the Company, and we remain committed to acting in your best interests. We are unwavering in our belief that by continuing to take the best next step, one after another, we will continue to hit key milestones in the coming year and, in the process, drive significant potential value for our shareholders.

My dedication to the Company is grounded in my belief that leronlimab has the potential to be a life-changing therapeutic. Our commitment is to drive value for you – the shareholders – and to bring better healthcare to patients in need.

Included below are updates on our top priorities. I am excited about CytoDyn's prospects moving forward and will provide additional updates as warranted.

Sincerely,

Dr. Jacob Lalezari

CEO

Oncology – September 2024 Updates

Our top priority remains the investigation of leronlimab in the field of oncology. As recently announced, CytoDyn is initiating a Phase II study of leronlimab in patients with relapsed/refractory micro-satellite stable colorectal cancer ("CRC"). Our synopsis proposal for the study was reviewed via a meeting with the FDA in August, and our final protocol is being submitted this week. We will continue to provide updates on this trial in the coming weeks, and expect to start screening patients in early 2025.

In addition to CRC, CytoDyn is investigating the role for leronlimab in two other oncology indications via strategic and low-cost research and development opportunities, and in collaboration with several reputable institutions. I am pleased to announce that CytoDyn is working with a team of experts to resume the exploration of Triple-Negative Breast Cancer ("TNBC"), including colleagues from the University of Hawaii Cancer Center, MD Anderson Cancer Center, and the Pennsylvania Cancer and Regenerative Medicine Research Center. We will be working with this team in the coming months to design and conduct a preclinical TNBC study that will aim to confirm the mechanism of action of leronlimab in oncology and address the question of potential synergies with both antibody-drug conjugates and immune checkpoint inhibitors. The Company intends to use this preclinical study to form the basis for a potential partnership and better inform the design of a follow-up clinical study in patients with metastatic TNBC.

Finally, the results from the preclinical Glioblastoma study in mice performed by the Albert Einstein College of Medicine should be released in the coming months.

Inflammation – September 2024 Updates

Within the past several weeks, we announced our selection of Syneos Health to serve as our clinical research organization ("CRO") and implement our FDA-approved protocol to evaluate leronlimab in the treatment of patients with HIV and chronic inflammation. This trial has been specifically designed to provide clarity around the precise mechanism of action of leronlimab on biomarkers during the treatment of chronic inflammation. We will continue to provide updates on this trial in the coming weeks, and expect to start screening patients in December 2024.

CytoDyn is pursuing two other clinical studies linked to inflammation. First, we are working on a pilot study of leronlimab in the treatment of patients with mild to moderate Alzheimer's Disease. The study will evaluate a neuroradiology primary endpoint to determine efficacy. We are also grateful to the foundation that has tentatively agreed to fund this study but wishes to remain anonymous at this time.

Finally, CytoDyn is also in the process of organizing a pilot study in patients with chronic

fatigue syndrome who demonstrate elevated markers of chronic inflammation. Additional information will be provided in future shareholder updates.

Other – September 2024 Updates

CytoDyn will soon receive results from a preclinical study of leronlimab in a mouse model of MASH. That study is meant to clarify the correct dosing of leronlimab in the MASH setting and address the question of potential synergy with Resmetirom, the only currently approved therapy for the treatment of MASH.

As previously announced, CytoDyn will be partnering with the American Foundation for AIDS Research (amfAR) to sponsor the HIV LATCH study which will use leronlimab to protect CCR5+ donor immune cells from HIV infection while aiming for a cure in the setting of bone marrow transplantation provided to an HIV+ recipient. It is the Company's belief that the likelihood of success of the LATCH program was greatly enhanced with the recent announcement by investigators in Germany of a successful HIV cure using stem cells from a donor who was heterozygous for the CCR5 delta-32 mutation. Indeed, those same investigators have reached out to CytoDyn and asked if they too can run a similar LATCH program at their research center in Berlin, and we are currently taking steps to make this opportunity a reality.

CytoDyn has also continued to pursue publication of our existing clinical data. The CD10 manuscript describing the leronlimab trial of patients with mild to moderate Covid-19 was recently accepted for publication by Clinical Therapeutics. The CD02 HIV paper, the CD12 manuscript on severe/critical Covid, the twin papers on the TNBC study results, and the MASH manuscript are all pending either final author review or final data confirmation prior to submission. All published research will be available on the Company's website, soon after publication.

Note Regarding Forward-Looking Statements

This letter and the accompanying Frequently Asked Questions supplement contain forward-looking statements relating to, among other things, future operating and financial performance, product development, market position 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.

CONTACT

Investor Relations
CytoDyn Inc.
ir@cytodyn.com

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