March 18, 2025

March 2025 Letter to Shareholders

VANCOUVER, Washington, March 18, 2025 (GLOBE NEWSWIRE) -- Dear Shareholders,

As envisioned, 2025 is unfolding to be an exciting year for CytoDyn Inc. (“CytoDyn” or the “Company”). On February 24, 2025, the Company announced increased survival rates in patients with metastatic Triple-Negative Breast Cancer (“mTNBC”) who were treated with leronlimab in prior CytoDyn-sponsored studies. The impressive survival observations at 12, 24, and 36 months in patients who previously failed treatment in the metastatic or locally advanced setting indicate leronlimab could play a significant role as a paradigm-shifting therapeutic in oncology. Of particular interest, we identified a subgroup of these patients who remain alive and well today and currently identify as cancer-free. This is only the beginning of the Company’s 2025 oncology story. We are eager to provide updates in the coming months as they are available to share. There is still much work to be done, but I am encouraged by what is on the near horizon.

I’d like to offer a word of deep gratitude to the CytoDyn team and the key opinion leaders (“KOLs”) who worked so diligently these last months to bring these data together. I would also like to reiterate my appreciation for you – the shareholders. Our business priorities are (i) getting leronlimab to patients in need; and (ii) generating value for our dedicated shareholders. As a long-time supporter of the company and now CEO, I believe investors deserve clear and direct updates as it relates to milestones, regulatory process, and finances. We will continue to incorporate this principle into our messaging as we move forward, presenting a clear picture of where we stand in the development pipeline and celebrating major milestones together. Looking ahead, we are excited to share more about the clarity forming around the putative mechanism of action of leronlimab in solid tumors, as well continued updates relating to the Colorectal Cancer (“CRC”) trial, as further described below.

In terms of the regulatory process, I am confident that our collaborative relationship with the FDA has placed us on a positive trajectory. To accelerate progress in oncology where feasible, we’re establishing an oncology advisory board to ensure we are exploring the fastest and most responsible pathway(s) forward. We will continue to look for opportunities to solicit feedback regarding our development process from both KOLs and the FDA. Maintaining strong relationships and credibility with the FDA and industry partners remains a top priority as we chart our future course.

The Company continues to be on track financially and we forecast sufficient cash and drug supply on hand to advance our clinical priorities in 2025. As we approach key milestones and announcements in the coming months, we’ll evaluate opportunities to raise additional funds at optimal times and through methods that best serve the Company and its shareholders. We believe leronlimab has already established the potential for tremendous value in the clinic, and in the coming months we look forward to sharing the basis for that conclusion.

In sum, the developments in oncology have set the stage for 2025 to be a benchmark year

for CytoDyn. This is no longer a platform drug in search of an indication; we now have compelling data to support a role for leronlimab in solid-tumor oncology and are executing on that vision.

With Gratitude,

Jacob Lalezari, MD
CEO

Oncology – March 2025 Update

The Company continues to prioritize oncology in 2025, as we believe this indication holds the highest potential and shortest timeline for return on investment in the form of a partnership or drug approval.

The exciting survival outcomes announced in February 2025 provide early clinical evidence of leronlimab's potential impact across the field of solid-tumor oncology. As previously announced, we've submitted our findings as an abstract to the European Society for Medical Oncology meeting in Munich, Germany in May 2025. We are eager to share additional insights into the apparent mechanism behind the survival outcomes and will do so once appropriate and in compliance with pre-conference publication and announcement allowances. In the meantime, CytoDyn has initiated a follow-up protocol so we can continue to monitor the surviving patients into the future.

The CytoDyn/Syneos study teams have now approved eight clinical sites and counting to participate in CytoDyn's Phase II study of patients with CRC and refractory disease. These clinical sites will include a mix of both large community practices as well as academic centers which all have well-established track records of superior work and high enrollment. With our clinical trial agreements in place and study initiation visits about to start, we expect screening of patients into the CRC study to commence shortly.

As previously mentioned, Dr. Ben Weinberg from Georgetown University and the MedStar Health Alliance will be the lead Principal Investigator for the CRC study. Per the FDA's request, the first five patients enrolled will receive 350 mg of leronlimab SQ once/week in combination with TAS-102 and bevacizumab. After a preliminary safety review by the Data and Safety Monitoring Board ("DSMB"), subsequent patients will be randomized to 350 or 700 mg of weekly leronlimab along with the same background regimen. The DSMB will perform a second safety review after the first 20 patients have completed at least 1 cycle of therapy and can then recommend restricting further enrollment to a single dose level, if deemed appropriate.

For additional information, the CRC study protocol is posted on the NCI Clinical Trials website, and can be viewed here.

In concert with the observation of prolonged survival in patients with mTNBC described above, CytoDyn remains focused on expeditiously resuming our clinical development in this indication. Two previously announced preclinical studies in TNBC that will identify treatment strategies to optimize the design of future studies are now underway. A third study has begun to further examine the apparent mechanism behind the observed increase in survival as compared to existing treatment paths. In the meantime, we will continue discussions with

KOLs about the possibility of initiating a follow-up study in patients with mTNBC on an abbreviated timeline, based on currently available data.

The Company also continues to explore the possible use of leronlimab in the treatment of glioblastoma multiforme ("GBM"). A preclinical study at the Albert Einstein College of Medicine sequencing temozolomide and leronlimab is now underway. CytoDyn is also in discussions with several KOLs in neuro-oncology about the possibility of initiating a pilot study in patients with GBM, also based on currently available data.

Inflammation – March 2025 Update

As previously announced, CytoDyn applied to the NIH/RECOVER-TLC group for the inclusion of leronlimab in their next round of Long Covid treatment studies. The shifting policy landscape in the United States has created some uncertainty around government-sponsored funding of research, but we have been informed by a member of the RECOVER team that their review process has resumed, and we expect a decision soon.

In addition, the protocol for a pilot study of leronlimab in the treatment of patients with mild to moderate Alzheimer's Disease ("AD") is now finalized. The study will take place at Cornell Medical Center in New York and will evaluate a neuroradiology endpoint that should provide a clear signal of leronlimab's potential role in treating AD. The study is fully funded, and our colleagues at Cornell are engaged to move the project forward through Cornell's institutional review process and FDA submission.

A new collaborator, Dr. Tom Carmichael, Professor and Chair of Neurology at the University of California, Los Angeles, has published important preclinical observations demonstrating how a small molecule CCR5 inhibitor can expedite recovery following a cerebrovascular accident ("CVA" or "stroke"). CytoDyn is working with Dr. Carmichael and Dr. Kate Schunke at the University of Hawaii to conduct a preclinical study of stroke in transgenic mice that express human CCR5. We are excited by this initiative, given our view that there is an unmet need for innovative and effective treatment paths for patients in this category, and our belief that the market for therapies to treat stroke and/or traumatic brain injury could grow significantly over the next several decades. Dr. Carmichael will also be advising on the pilot study of AD to be initiated at Cornell Medical Center in New York.

As announced via press release on February 6, 2025, the final results from SMC Laboratories ("SMC") indicated statistically significant reversal of liver fibrosis ($p< 0.01$) in all 3 studies conducted at SMC. Importantly, the reversal of fibrosis appears to be independent of the mechanism of liver insult, as the effect was seen in both metabolic-dysfunction associated steatohepatitis ("MASH") and CCL4 models of liver injury. To call attention to a key point of clarification, the final results at SMC did not confirm a significant effect of leronlimab on fat accumulation in the liver in the MASH model. Given this observation, we will pause development efforts related to MASH in the near term. Instead, we are continuing discussions with potential partners who have expressed interest in funding studies of leronlimab in the treatment of patients with organ fibrosis to build on the promising findings listed above.

Other – March 2025 Update

As previously announced, CytoDyn is partnering with the American Foundation for AIDS

Research (“amfAR”) to sponsor an HIV cure study called LATCH (Leronlimab in Allogenic stem cell Transplant to Cure HIV). The clinical teams at Oregon Health and Sciences University and the University of Washington remain confident in the chances of success of their LATCH protocol and we look forward to the launch of this program in 2025.

CytoDyn continues to prioritize the publication of our clinical data. The exciting observation of improved survival in patients with mTNBC treated with leronlimab has naturally prompted us to reframe the focus of our oncology manuscripts. Submission of these oncology manuscripts for peer review is a top publication priority. Additional ongoing publication efforts include:

- The manuscript for our CD02 Phase 3 study in patients with multi-drug-resistant HIV was recently published by the *Journal of Acquired Immune Deficiency Syndromes* and has been posted to our website.
- The manuscripts for the CD12 Acute Covid and MASH clinical studies are in final preparation for submission.
- A manuscript summarizing the results of treatment with leronlimab on liver fibrosis from SMC is in preparation.
- As previously announced, CytoDyn is preparing a manuscript summarizing the integrated safety data from the almost 1,600 patients who have already received leronlimab. The final draft of that safety summary will be completed shortly.

Note Regarding Forward-Looking Statements

This letter contains forward-looking statements relating to, among other things, clinical drug development and research 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 Part I, Item 1A, as well as subsequent reports filed with the Securities and Exchange Commission. CytoDyn Inc. does not undertake to update any forward-looking statements as a result of new information or future events or developments other than as required by law.

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