



Leronlimab (350 mg) Weekly Use for 14 Weeks in Open Label Arm of NASH Trial Produces Fibrosis Reduction as High as 93 msec Amongst First 15 Patients with Average Reduction of 24 msec

The 60 double-blinded arm (700 mg) will be unblinded by early December

VANCOUVER, Wash.--(BUSINESS WIRE)-- CytoDyn Inc. (OTCQB: CYDY) ("CytoDyn" or the "Company"), a late-stage biotechnology company developing leronlimab, a CCR5 antagonist with the potential for multiple therapeutic indications, today reported data from its trial treating NASH (nonalcoholic steatohepatitis) open label with leronlimab.

Leronlimab open label NASH results continue to show reductions in fat and fibrosis suggestive of a potential therapy not only for NAFLD (Non-Alcoholic Fatty Liver Deposit) but also in NASH. Fat reductions by proton density fat fraction PDFF up to 45% along with reductions in fibrosis up to 8% by CT1 were noted from baseline after just 14 weeks of treatment. The reductions in fibrosis were seen in both severe and mild-moderate NASH cases.

Nader Pourhassan, Ph.D., CytoDyn's President and Chief Executive Officer, stated, "Though numerous drugs have been evaluated in clinical trials, there have been no approvals by the U.S. Food and Drug Administration for treating biopsy-proven NASH. We are encouraged by the continued results and look forward to presenting the full trial results after database lock. We believe this reported data is an exciting step forward in research and demonstrates the potential of leronlimab for inhibiting the liver fibrosis associated with NASH. CytoDyn will now file for Fast Track Designation for both the indications of NASH and NAFLD. Once the full results are reported, which we anticipate to be available in mid-December, we may proceed to file a Phase 3 protocol with the FDA and request accelerated approval."

About CytoDyn

CytoDyn is a late-stage biotechnology company developing innovative treatments for multiple therapeutic indications using leronlimab, a novel humanized monoclonal antibody targeting the CCR5 receptor. CCR5 plays a critical role in the ability of HIV to enter and infect healthy T-cells and appears to be implicated in tumor metastasis and immune-mediated illnesses, such as NASH.

CytoDyn successfully completed a Phase 3 pivotal trial using leronlimab combined with standard antiretroviral therapies in HIV-infected patients who were heavily treatment-

experienced individuals with limited treatment options. CytoDyn is working diligently to resubmit its BLA for this HIV combination therapy since receiving a Refusal to File in July 2020. In July 2021, CytoDyn announced that it had submitted a dose justification report to the FDA, an integral step in the resubmission process for its BLA, which it expects to complete by the end of the first quarter of calendar 2022. CytoDyn also completed a Phase 2b/3 investigative trial with leronlimab used as a once-weekly monotherapy for HIV-infected patients. CytoDyn plans to initiate a registration-directed study of leronlimab monotherapy indication. If successful, it could support a label expansion approval. Clinical results to date from two trials have shown that leronlimab can maintain a suppressed viral load in a sub-population of R5 HIV patients who chose to switch from their daily pills regimen to once-a-week subcutaneous dose of leronlimab. Several patients on leronlimab's Phase 2b extension arm have remained virally suppressed for almost 7 years and many patients in our Phase 2b/3 investigative trial are passing two and some four years of monotherapy with suppressed viral load.

CytoDyn recently completed a Phase 2 clinical trial with leronlimab in mTNBC and a Phase 2 basket trial in solid tumor cancers (22 different cancer indications) A Phase 2 investigative trial for post-acute sequelae of SARS COV-2, also known as COVID-19 long-hauler's, and a Phase 2 clinical trial for NASH are continuing. CytoDyn has already completed a Phase 2 and Phase 3 trial for mild-to-moderate and severe-to-critical COVID-19 patients, respectively, for which CytoDyn did not meet its primary or secondary endpoints, except for the secondary endpoint in the critically ill subpopulation. More information is at www.cytodyn.com.

Forward-Looking Statements

This press release contains certain forward-looking statements that involve risks, uncertainties and assumptions that are difficult to predict. Words and expressions reflecting optimism, satisfaction or disappointment with current prospects, as well as words such as "believes," "hopes," "intends," "estimates," "expects," "projects," "plans," "anticipates" and variations thereof, or the use of future tense, identify forward-looking statements, but their absence does not mean that a statement is not forward-looking. Forward-looking statements specifically include statements about leronlimab, its ability to provide positive health outcomes, the possible results of clinical trials, studies or other programs or ability to continue those programs, the ability to obtain regulatory approval for commercial sales, and the market for actual commercial sales. The Company's forward-looking statements are not guarantees of performance, and actual results could vary materially from those contained in or expressed by such statements due to risks and uncertainties including: (i) the regulatory determinations of leronlimab's efficacy to treat human immunodeficiency virus ("HIV") patients with multiple resistance to current standard of care, COVID-19 patients, and metastatic Triple-Negative Breast Cancer ("mTNBC"), among other indications, by the U.S. Food and Drug Administration and various drug regulatory agencies in other countries; (ii) the Company's ability to raise additional capital to fund its operations; (iii) the Company's ability to meet its debt obligations; (iv) the Company's ability to enter into partnership or licensing arrangements with third-parties; (v) the Company's ability to identify patients to enroll in its clinical trials in a timely fashion; (vi) the Company's ability to achieve approval of a marketable product; (vii) the design, implementation and conduct of the Company's clinical trials; (viii) the results of the Company's clinical trials, including the possibility of unfavorable clinical trial results; (ix) the market for, and marketability of, any product that is approved; (x)

the existence or development of vaccines, drugs, or other treatments that are viewed by medical professionals or patients as superior to the Company's products; (xi) regulatory initiatives, compliance with governmental regulations and the regulatory approval process; (xii) legal proceedings, investigations or inquiries affecting the Company or its products; (xiii) general economic and business conditions; (xiv) changes in foreign, political, and social conditions; (xv) stockholder actions or proposals with regard to the Company, its management, or its board of directors; and (xvi) various other matters, many of which are beyond the Company's control. The Company urges investors to consider specifically the various risk factors identified in its most recent Form 10-K, and any risk factors or cautionary statements included in any subsequent Form 10-Q or Form 8-K, filed with the Securities and Exchange Commission. Except as required by law, the Company does not undertake any responsibility to update any forward-looking statements to take into account events or circumstances that occur after the date of this press release.

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Source: CytoDyn Inc.