



CytoDyn Research Paper on Leronlimab Published in Frontiers in Immunology Journal

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 announced that its research paper entitled "CCR5 receptor occupancy analysis reveals increased peripheral blood CCR5+CD4+ T cells following treatment with the anti-CCR5 antibody Leronlimab" has been accepted by Frontiers in Immunology, a leading journal in its field publishing rigorously peer-reviewed research across basic, translational and clinical immunology.

The article can be found here:

http://journal.frontiersin.org/article/10.3389/fimmu.2021.794638/full?utm_source=Email_to_authors&utm_medium=Email&utm_content=T1_11.5e1_author&utm

Importantly, the results of the study outlined in the research paper:

1. Establish two CCR5 receptor occupancy calculation methods for longitudinal monitoring of anti-CCR5 therapeutic antibody blockade efficacy in both macaques and humans;
2. Demonstrate that CCR5+CD4+ T cell levels temporarily increase with leronlimab treatment; and
3. Facilitate future detailed investigations into the immunological impacts of CCR5 inhibition in multiple pathophysiological processes.

"We are thrilled that the Frontiers in Immunology journal has published this important paper to inform further the scientific community of these exciting developments with leronlimab," said CytoDyn's Chief Medical Officer, Scott A. Kelly M.D. "We will relentlessly pursue the various indications for leronlimab to realize its full therapeutic potential. Our continued work on the mechanism of action of leronlimab continues to lay the foundation for more exciting opportunities of leronlimab for patients and our shareholders."

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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