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CytoDyn Submits Dose Justification Report to FDA to Begin Overcoming Deficiencies in its BLA for HIV

Management works to advance its BLA filing seeking FDA approval for leronlimab as a combination therapy for HIV patients while continuing its evaluation of other potential indications

VANCOUVER, Washington, July 01, 2021 (GLOBE NEWSWIRE) -- **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, announced today it has submitted a dose justification report to the U.S. Food and Drug Administration ("FDA"), which will be followed by an official submission to CytoDyn's IND. This is an integral step in the resubmission process for the Biologics License Application ("BLA") for HIV patients with multiple resistance to current standard of care. The dose justification report is a key component for the BLA and includes receptor occupancy analysis, among other factors, to determine the optimal marketed dose for leronlimab. Following FDA feedback on this critical step, CytoDyn will begin submission of BLA modules by specified timelines in accordance with FDA guidance and approval. This update is consistent with our intent and commitment to keep CytoDyn investors informed of critical developments.

Chris Recknor, M.D., CytoDyn's Chief Operating Officer and Head of Clinical Development, commented, "Our team has done a great job and remains focused on the goal of a BLA for HIV. We have a great molecule with many opportunities being evaluated in parallel to the BLA, including COVID, NASH and Oncology. We are on track for the top line report for the COVID-19 long-haulers symptoms/biomarker trial and will soon start two COVID-19 trials in Brazil. Our Phase 2 NASH trial has enrolled the 60th patient on schedule. We are working on our CCR5 solid tumor cancers basket trial and our triple-negative breast cancer dose escalation portion is completed with the main trial beginning in July. We are very excited about all we have ahead of us this year."

Nader Pourhassan, Ph.D., CytoDyn's President and Chief Executive Officer, concluded, "Dr. Recknor and the team he has assembled in a short period of time continue to comprehensively address the previously noted deficiencies in our initial BLA submission, while concurrently pushing forward with our complete agenda for 2021. The HIV BLA is a significant undertaking, and we are very encouraged about our progress. Since the commencement of clinical trials with leronlimab about 7 years ago, we have positioned leronlimab for potential approval for multiple indications, namely, 22 solid tumor cancers, NASH, and three indications in COVID-19, and the opportunities continue to grow."

About Leronlimab

The U.S. Food and Drug Administration (FDA) granted CytoDyn Fast Track designation to explore two potential indications using leronlimab to treat Human Immunodeficiency Virus (HIV) and metastatic cancer. The first indication is combination therapy with HAART for HIV-infected patients, and the second is for metastatic triple-negative breast cancer (mTNBC). Leronlimab is an investigational humanized IgG4 mAb that binds to CCR5, a cellular receptor important in HIV infection, tumor metastases, and other diseases, including nonalcoholic steatohepatitis (NASH). Leronlimab has been studied in 16 clinical trials involving more than 1,200 people and met its primary endpoints in a pivotal Phase 3 trial (leronlimab combined with HIV standard care in patients with multi-drug resistance to current available classes of HIV drugs).

Leronlimab, among various potential applications, is a viral-entry inhibitor in HIV/AIDS. It binds to CCR5, thus protecting healthy T cells from viral infection by blocking the predominant HIV (R5) subtype from entering those cells. Leronlimab does not work on other strains of HIV (for example X4), however, R5 is the most dominant strain of HIV. Five clinical trials have demonstrated leronlimab could significantly reduce or control HIV viral load in humans. The leronlimab antibody appears to be a powerful antiviral agent with fewer side effects and less frequent dosing requirements than currently used daily drug therapies. Cancer research has shown CCR5 may play a role in tumor invasion, metastases, and tumor microenvironment control (for example, through angiogenesis). Published studies have shown that blocking CCR5 can reduce tumor metastases in laboratory and animal models of aggressive breast and prostate cancer. Leronlimab reduced human breast cancer metastasis by more than 97% in a murine xenograft model. As a result, CytoDyn is conducting two clinical trials, one, a Phase 1b/2 in mTNBC, which was granted Fast Track designation by the FDA in 2019, and a second, a Phase 2, basket trial which encompasses 22 different solid tumor cancers.

The CCR5 receptor plays a central role in modulating immune cell trafficking to sites of inflammation. After completing two clinical trials with COVID-19 patients (a Phase 2 and a Phase 3), CytoDyn initiated a Phase 2 investigative trial for post-acute sequelae of SARS COV-2 (PASC), also known as COVID-19 Long-Haulers. This trial will evaluate the effect of leronlimab on clinical symptoms and laboratory biomarkers to further understand the pathophysiology of PASC. It is currently estimated that between 10-30% of those infected with COVID-19 develop long-term sequelae. Common symptoms include fatigue, cognitive impairment, sleep disorders, and shortness of breath. If this trial is successful, CytoDyn plans to pursue clinical trials to evaluate leronlimab's effect on immunological dysregulation in other post-viral syndromes, including myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS).

CytoDyn is also conducting a Phase 2 clinical trial for NASH to evaluate the effect of leronlimab on liver steatosis and fibrosis. Preclinical studies revealed a significant reduction in NAFLD and a reduction in liver fibrosis using leronlimab. There are currently no FDA approved treatments for NASH, which is a leading cause of liver transplant. About 30 to 40 percent of adults in the U.S. live with NAFLD, and 3 to 12 percent of adults in the U.S. live with NASH. There have been no strong safety signals identified in patients administered leronlimab in multiple disease spectrums, including patients with HIV, COVID-19, and oncology.

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 2b pivotal trial using leronlimab combined with standard antiretroviral therapies in HIV-infected patients who were heavily treatment-experienced individuals with limited treatment options. CytoDyn has been working diligently to resubmit its Biologics License Application ("BLA") for this HIV combination therapy since receiving a Refusal to File in July 2020 and subsequently meeting with the FDA telephonically to address their written guidance concerning the filing. CytoDyn expects to begin to resubmit its BLA shortly after the first half of calendar 2021. 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 extension approval. Clinical results to date from two trials have shown that leronlimab can keep the viral load suppressed 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 is also conducting a Phase 2 clinical trial with leronlimab in mTNBC, a Phase 2 basket trial in solid tumor cancers (22 different cancer indications), Phase 2 investigative trial for post-acute sequelae of SARS COV-2, also known as COVID-19 long haulers, and a Phase 2 clinical trial for NASH. 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 determination of leronlimab's efficacy to treat HIV patients with multiple resistance to current standard of care and COVID-19 patients, 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, if any, (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) general economic and business conditions, (xiii) changes in foreign, political, and social conditions, and (xiv) 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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