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CytoDyn Granted a Significant Patent by USPTO for Methods of Treating Coronavirus Infection with Leronlimab

VANCOUVER, Washington, July 06, 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 its drug candidate, leronlimab, has been granted U.S. Patent No. 11,045,546 by the U.S. Patent and Trademark Office ("USPTO") for methods of treating coronavirus infection (the "Patent").

The Patent is owned by CytoDyn and its term of protection is expected to extend at least until June 15, 2040. The USPTO prioritized examination of CytoDyn's patent application, resulting in the grant of this Patent under the USPTO's COVID-19 Prioritized Examination Pilot Program in just about one (1) year.

The Patent discloses methods of treating hyperinflammation—a common complication of COVID-19 caused by SARS-CoV-2 coronavirus infection.

The granted claims relate to methods of facilitating normalization of the CD4 T cell/CD8 T cell ratios or increasing CD8 T cell frequency in SARS-CoV-2 infected subjects, comprising administering leronlimab or a binding fragment thereof. The treated subjects may include those having mild, moderate, or severe COVID-19, exhibiting no symptoms associated with COVID-19, or having cytokine release syndrome, acute respiratory distress syndrome (ARDS), hemophagocytic lymphohistiocytosis (HLH), or macrophage activation syndrome. Further, the claimed methods include options for administering one or more additional therapeutic agents to the subject (e.g., an antiviral agent, a non-CCR5 immunomodulatory agent, a CCL5 binding agent, an immune checkpoint molecule inhibitor, or any combination thereof).

Scott Kelly, M.D., CytoDyn's Chief Medical Officer and Chairman of the Board, commented, "We are very pleased that the USPTO has recognized the beneficial clinical outcomes through the granting of this important patent. We are continuing to document numerous biomarkers through laboratory analyses to further support the clinical outcomes demonstrated by the patients in our trials and are confident this will further advance our regulatory goals in the U.S. and abroad."

Nader Pourhassan, Ph.D., CytoDyn's President and Chief Executive Officer, concluded, "The collaboration among our clinicians and our legal team continues to underscore the multiple opportunities for leronlimab, and we are dedicated to making leronlimab available to patients of the world for many indications. Our steady push to reach the finish line includes our BLA for HIV, which we believe to be back on track, pursuit of Breakthrough Therapy

designation based on significant positive results from our COVID-19 long-haulers trial (CD15), initiation of two COVID-19 trials in Brazil in the near future, reaching the targeted enrollment of 60 patients in our Phase 2 NASH trial ahead of the previously scheduled timeline with trial results expected before yearend, and many more developments anticipated later this year."

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 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 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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