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CytoDyn Receives First Purchase Order from Chiral Pharma Corporation for Use of Leronlimab Under CSP for COVID-19 Patients in the Philippines

Chiral is simultaneously working on application for Emergency Use Authorization

VANCOUVER, Washington, June 01, 2021 (GLOBE NEWSWIRE) -- **CytoDyn Inc. (OTC.QB: CYDY)**, (“CytoDyn” or the “Company"), a late-stage biotechnology company developing Vyrologix™ (leronlimab-Pro 140), a CCR5 antagonist with potential multiple therapeutic indications, announced today that Chiral Pharma Corporation in the Philippines placed its first purchase order for leronlimab under a Compassionate Special Permit (“CSP”) to treat critically ill COVID-19 patients in the Philippines. The Company expects to recognize revenues related to this purchase order upon fulfillment of the purchase order and the terms of the agreement.

Chris Recknor, M.D., Chief Operating Officer and Head of Clinical Development of CytoDyn, said, "Current Philippine CSP data is significant for 21% mortality rate which is below that observed in CD12. One of the patient successes was recently reported last week on One News Philippines TV station. This patient had severe COVID-19 with deteriorating lung function despite treatment with antivirals and steroids. Testing was significant for high inflammation in the blood with Ferritin 17x elevated. Oxygen saturation on maximum oxygen flow was only 82% (normal >95%). Twenty hours after receiving 700 mg of leronlimab subcutaneously at the patient's home, the patient's heart rate decreased from 120s to low 90s. Shortly thereafter the patient regained appetite, improved lung function, and had reduced inflammation with Ferritin down to 4x elevated. At week two, the patient successfully went off oxygen shortly after second dose also given at home. At week three, the patient continued to improve in stamina and returned to routine physical activities. Inflammation markers were still elevated with Ferritin still two times elevated, so a third dose was given. At week four, the patient is currently back to normal life activities."

Dr. Recknor further stated, “Although the CSP data is not randomized double-blinded control, the numerous case reports from the Philippine CSP are consistent with CD12 prespecified major endpoint metrics showing Vyrologix when combined with standard of care is better than standard of care alone (e.g. antivirals/dexamethasone) and may improve clinical outcome status four times better than standard of care at day 14 ($p< 0.021$) and reduce hospital stay by as much as 6 days ($p<0.005$) with a higher likelihood of returning to activities of daily living without limitations vs. placebo control in critical COVID patients."

Nader Pourhassan, Ph.D., President and Chief Executive Officer of CytoDyn, stated, “After we provided leronlimab, free of charge, for the first 100 patients in the Philippines for

critically ill COVID-19 patients, we are now on a clear path to achieving revenue with our first purchase order today under CSP from Chiral Pharma. We are so proud to be able to provide leronlimab in the capital region where the use of intensive care unit (ICU) capacity is above 70% for COVID-19 patients with hospital beds in great shortage. We are equally excited about our EUA package (CMC, non-clinical and clinical sections) being prepared for submission to the Philippine FDA."

About Vyrologix™ (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 amongst many things, 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. NASH 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 has 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 refile 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 refile its BLA in the first half of the calendar year 2021 or shortly thereafter. 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. 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 financial results (including revenues, expenses, liquidity and cash flow), 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 sufficiency of the Company's cash position, (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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