May 3, 2021

# CytoDyn HIV Indication Update: Leronlimab HIV Extension Arm Nearing 7 Years with Continued Excellent Safety Results

*Following the successful conclusion of three clinical trials, approximately 120 patients continue treatment with leronlimab in extension arms*

VANCOUVER, Washington, May 03, 2021 (GLOBE NEWSWIRE) -- **CytoDyn Inc. (OTC.QB: CYDY)**, ("CytoDyn" or the "Company"), a late-stage biotechnology company developing leronlimab (Vyrologix™ or PRO 140), a CCR5 antagonist with the potential for multiple therapeutic indications, announced today a comprehensive update on three continuing extension studies with leronlimab as a treatment for HIV.

Chris Recknor, M.D., CytoDyn's Chief Operating Officer, commented, "We are still on schedule for rolling submission of the HIV BLA in July of this year. Clinical results from multiple trials show that Vyrologix can significantly reduce the viral burden in people infected with HIV. Moreover, a Phase 2 clinical trial demonstrated that Vyrologix monotherapy could prevent viral escape in HIV-infected patients. CytoDyn has gained tremendous insight in the safety of Vyrologix through extension of their three core HIV trials. There have been 66 patients from the original trials still receiving Vyrologix in an open label design with an exposure range of 4-7 years. No significant adverse safety issues reported. Vyrologix mechanism of inhibition is unique compared to other CCR5 antagonist agents because the binding is competitive rather than allosteric and takes place on the N-terminal and second loop of CCR5. While we are learning more about the unique binding of Vyrologix to CCR5 and how this impacts efficacy in other indications, including COVID and oncology, safety data from our cumulative trials remains excellent for almost 7 years and close to 1,200 patients."

Nader Pourhassan, Ph.D., President and Chief Executive Officer, noted, "With our BLA for HIV treatment on track with full support, we can now explore all other indications of Vyrologix (leronlimab) in parallel. While we will not slow down the cancer, NASH, COVID-19 (three different populations) and HIV combination therapy, we will expedite HIV monotherapy and PrEP, as well as a stroke trial this year. Our solid team for our clinical trials under Drs. Recknor, Kelly, and myself, along with our rock-solid team for manufacturing of leronlimab under the leadership of Dr. Nitya Ray, gives us strong confidence we will continue to make impressive progress. Leronlimab is a powerful product in the hands of a very capable team."

**About Leronlimab (PRO 140)**
Leronlimab has been studied in 11 clinical trials involving more than 1,200 people and met its primary endpoints in a pivotal Phase 3 trial (leronlimab combined with standard antiretroviral

therapies in HIV-infected treatment-experienced patients).

Leronlimab is a viral-entry inhibitor in HIV/AIDS. It masks CCR5, thus protecting healthy T cells from viral infection by blocking the predominant HIV (R5) subtype from entering those cells. Nine 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.

CytoDyn has successfully completed a Phase 3 pivotal trial using leronlimab combined with standard antiretroviral therapies in HIV-infected treatment-experienced patients. CytoDyn has been working diligently to resubmit its Biologics License Application ("BLA") for this HIV combination therapy since receiving a Refusal to File letter in July 2020 and subsequently meeting with the FDA telephonically to address their written guidance concerning the submission. CytoDyn expects to resubmit its BLA via a rolling submission starting in the third quarter of calendar 2021.

**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 appears to play a critical role in the ability of HIV to enter and infect healthy T-cells. 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 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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Source: CytoDyn Inc.