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CytoDyn Reaches Agreement with Albert Einstein Israelite Hospital in Brazil to Conduct Two COVID-19 Trials - a Small Trial in Critically Ill and a Large Trial in Severe Populations

Interim analysis for critically ill population will be conducted when enrollment reaches about 120 patients or 40% of the approximate 300 patients

VANCOUVER, Washington, May 05, 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 the agreement to partner with Academic Research Organization (ARO) - Albert Einstein Israelite Hospital (AEIH) in São Paulo, Brazil for two COVID-19 trials.

The COVID-19 trials in Brazil are intended to provide the Brazilian regulatory authority, ANVISA, with the requisite data to consider advancing the availability of leronlimab to thousands of Brazilians infected with COVID-19. These two Phase 3 trials will be conducted in up to 45 clinical sites.

Chris Recknor, M.D., CytoDyn’s Chief Operating Officer and Head of Clinical Development, commented, “We are pleased to partner with one of the best hospitals in Latin America, the Albert Einstein Israelite Hospital and their affiliated academic research organization network. This ARO has conducted multiple large-scale COVID trials for many pharmaceutical companies. CytoDyn is utilizing their extensive experience to develop and conduct our CD16 and CD17 COVID-19 trials. With approximately 1,500 patients in total for both trials, we anticipate having adequate power in each trial to achieve a significant p-value for our endpoints and will be performing an interim analysis after 40% of the critically ill patients are enrolled. In Brazil, the P1 COVID variant is fueling a second wave worse than the initial outbreak. In April, more than 78,000 people lost their lives from COVID and ICU capacity in 15 of Brazil’s 26 states, is at or above 90% full. Vyrologix is variant agnostic. We expect an interim analysis will be conducted in October-November of this year. We look forward to accelerating these trials for the benefit of the Brazilian people.”

Nader Pourhassan, Ph.D., CytoDyn’s President and Chief Executive Officer, added, “This agreement represents the relentless effort of the CytoDyn team with the Albert Einstein Israelite Hospital team. Dr. Christopher Recknor and many other CytoDyn team members did a fantastic job getting this protocol to its final form. We also thank the BIOMM team of Brazil for presenting this opportunity to us. Without their involvement, this could not have

been possible. We believe the critically ill population study will remove the final obstacle for us to receive EUA not only in Brazil, but potentially all over the world. We believe this is the most promising study in our company's history, as we now have generated important information to give ourselves the perfect opportunity to potentially obtain leronlimab's first approval. We look forward to updating all of our stockholders later today regarding these two studies, along with other developments."

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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