March 30, 2022

CytoDyn Announces Partial Clinical Hold of HIV Program and Full Clinical Hold of COVID-19 Program

Live webcast to be held March 31 discussing announcement

VANCOUVER, Washington, March 30, 2022 (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 that the U.S. Food and Drug Administration (FDA) has placed a partial clinical hold on its HIV program and a full clinical hold on its COVID-19 program in the United States. Further, the Company elected to pause its Brazil COVID-19 trials pending results from its previously scheduled data safety monitoring committee meeting and is in the process of reevaluating the timing of its HIV BLA resubmission.

The Company was not enrolling any new patients in the trials placed on hold in the United States. The partial clinical hold on the HIV program impacts patients currently enrolled in extension trials. These patients will be transitioned to other available therapeutics and no clinical studies can be initiated or resumed until the partial clinical hold is resolved. CytoDyn intends to work closely with the FDA to resolve the partial clinical hold as soon as possible. Under the full clinical hold on the COVID-19 program, no new clinical studies may be initiated until the clinical hold is resolved. The Company is not currently conducting any COVID-19 trials in the United States, as it is evaluating the most optimal programs on which to focus its resources and attention.

“CytoDyn is committed to FDA compliance,” said Scott A. Kelly, M.D., Chief Medical Officer of CytoDyn. “We are evaluating our clinical programs and are working to resolve the issues underlying the clinical holds as soon as possible in close communication with the FDA. We will provide an update when we have additional information.”

The Company will host a webcast conference call to discuss this announcement and other updates on March 31, 2022 at 5:30 AM (PT) and 8:30 AM (ET). Connection details are provided below:

Date: Thursday, March 31, 2022
Time: 5:30 AM PT / 8:30 AM ET
Access: https://services.choruscall.com/mediaframe/webcast.html?webcastid=v9IRoWUq
Questions: Prior to the webcast, questions can be submitted online to ir@cytodyn.com

About CytoDyn

CytoDyn is a clinical-stage biotechnology company focused on the development and

commercialization of leronlimab, an investigational humanized IgG4 monoclonal antibody (mAb) that is designed to bind to C-C chemokine receptor type 5 (CCR5), a protein on the surface of certain immune system cells that is believed to play a role in numerous disease processes. Cytodyn is studying leronlimab in multiple therapeutic areas, including infectious disease, cancer, and autoimmune conditions.

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, the Company's ability to resolve the clinical holds recently imposed by the FDA, leronlimab's safety and effectiveness, and the Company's ability to obtain regulatory approval for 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 determinations of leronlimab's safety and effectiveness to treat the diseases and conditions for which we are studying the product by the U.S. Food and Drug Administration (FDA) 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; (iv) the Company's ability to recruit a permanent CEO and retain other key employees; (v) the Company's ability to enter into partnership or licensing arrangements with third-parties; (vi) the Company's ability to identify patients to enroll in its clinical trials in a timely fashion; (vii) the timely and sufficient development, through internal resources or third-party consultants, of analyses of the data generated from the Company's clinical trials required by the FDA or other regulatory agencies in connection with the Company's BLA resubmission for the HIV indication or other applications for approval of the Company's drug product; (viii) the Company's ability to achieve approval of a marketable product; (ix) the design, implementation and conduct of the Company's clinical trials; (x) the results of the Company's clinical trials, including the possibility of unfavorable clinical trial results; (xi) the market for, and marketability of, any product that is approved; (xii) 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; (xiii) regulatory initiatives, compliance with governmental regulations and the regulatory approval process; (xiv) legal proceedings, investigations or inquiries affecting the Company or its products; (xv) general economic and business conditions; (xvi) changes in foreign, political, and social conditions; (xvii) stockholder actions or proposals with regard to the Company, its management, or its board of directors; and (xviii) 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 subsequent Form 10-Qs and Form 8-Ks, 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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