

# CytoDyn Announces FDA Has Lifted Clinical Hold

## Webcast to Provide Company Update on March 5, 2024

VANCOUVER, Washington, Feb. 29, 2024 (GLOBE NEWSWIRE) -- **CytoDyn Inc. (OTCQB: CYDY)** ("CytoDyn" or the "Company"), a biotechnology company developing leronlimab, a CCR5 antagonist with the potential for multiple therapeutic indications, announced today that the FDA has lifted the clinical hold on leronlimab. The Company is now free to proceed with its proposed HIV clinical trial exploring leronlimab and its effects on chronic inflammation.

CytoDyn's CEO, Dr. Jacob Lalezari, stated, "We are excited that the clinical hold on leronlimab has been lifted by the FDA. CytoDyn is grateful for the FDA's guidance on our protocol and we are excited to open a new chapter in the development of leronlimab as a therapy that provides clinical benefit by modulating chronic inflammation."

Dr. Lalezari will host an investment community webcast to provide a Company update on Tuesday, March 5, 2024. The update will include a discussion about the Company's clinical trial goals and expectations, upcoming publications, and overall development strategy moving forward.

**Date:** Tuesday, March 5, 2024

**Time:** 9:00 am PT / 12:00pm ET

**Access:** <https://event.choruscall.com/mediaframe/webcast.html?webcastid=KP5lRea9>

This is a livestream presentation. Participants are encouraged to login early prior to the start of the event. The replay will be available approximately 60 minutes after the conclusion of the webcast and can be accessed via the above link until at least April 5, 2024. The Company will not be conducting a Q&A session on this update call. However, please feel free to submit your questions to the Company via email to: [ir@cytodyn.com](mailto: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 has studied 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 may include statements about leronlimab, its ability to provide positive health outcomes, the Company's ability to implement a successful operating strategy for the development of leronlimab and thereby create shareholder value, the ability to obtain regulatory approval of the Company's drug products for commercial sales, and the strength of the Company's leadership team. 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 (the "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 and other payment obligations; (iv) the Company's ability to recruit and retain key employees; (v) the Company's ability to enter into partnership or licensing arrangements with third parties; (vi) 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 applications for approval of the Company's drug product; (vii) the Company's ability to achieve approval of a marketable product; (viii) the design, implementation and conduct of the Company's clinical trials; (ix) the results of any such clinical trials, including the possibility of unfavorable clinical trial results; (x) the market for, and marketability of, any product that is approved; (xi) 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; (xii) regulatory initiatives, compliance with governmental regulations and the regulatory approval process; (xiii) legal proceedings, investigations or inquiries affecting the Company or its products; (xiv) general economic and business conditions; (xv) changes in foreign, political, and social conditions; (xvi) stockholder actions or proposals with regard to the Company, its management, or its board of directors; and (xvii) 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 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.

## **CONTACT**

Investor Relations

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Source: CytoDyn Inc.