February 1, 2024

CytoDyn Announces Submission of Clinical Protocol to FDA and Initiation of Pre-Clinical Study in Glioblastoma

VANCOUVER, Washington, Feb. 01, 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 Company has submitted its revised HIV clinical trial protocol to the FDA. The Company believes this submission will lead to the removal of the clinical hold currently in effect.

CytoDyn's CEO, Dr. Jacob Lalezari stated, "Our HIV protocol has been revised and resubmitted following FDA input, and will study leronlimab in HIV patients who have increased inflammation and immune activation, which causes heart attacks, strokes, and other vascular events. We believe this protocol will help clarify the mechanisms by which leronlimab can be used as an immune modulator in HIV and a variety of other therapeutic areas."

In addition, the Company announced that its research partnership with Albert Einstein College of Medicine and Montefiore Medical Center is moving forward with a pre-clinical trial designed to study leronlimab in glioblastoma, a common and often untreatable form of primary brain cancer. Initial preparations have commenced for a trial to take place in 2024, one of potentially several pre-clinical trials to be conducted with Montefiore Medical Center.

As to the partnership with Montefiore Medical Center, Dr. Lalezari stated, "I am excited to start this pre-clinical trial with Albert Einstein College of Medicine and Montefiore Medical Center in New York. Glioblastoma is a common and often untreatable form of primary brain cancer. CytoDyn is fortunate to be able to evaluate the potential effects of leronlimab in a pre-clinical model of this all too often deadly cancer."

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.

About CytoDyn's Partnership with Albert Einstein College of Medicine and Montefiore Medical Center

In December 2023, the Company entered a partnership with Albert Einstein College of Medicine and Montefiore Medical Center, located in New York. The Company will be

providing leronlimab to support a pre-clinical trial evaluating the efficacy of leronlimab independently and in combination with temozolomide in treating glioblastoma multiforme, also known as grade IV astrocytoma (“GBM”) in infected humanized mice. The study will involve three groups of humanized mice: one control group, one group that will receive only leronlimab, and another group that will receive a combination of leronlimab and temozolomide. The primary objective of this study is to evaluate the effect of leronlimab on the primary tumor growth and occurrence of metastases on CCR5+ and CCR5- cells in humanized mice. Upon completion of the study, the academic institutions will provide the Company with a research report outlining the study results, and they will have the right to publish and present the study results. GBM is the most common type of primary malignant brain tumor and is aggressive and fast-growing. This study is expected to take place in the 2024 calendar year.

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 resolve the clinical hold imposed by the U.S. Food and Drug Administration (the “FDA”), 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 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.

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