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CytoDyn Announces President Takes Medical Leave of Absence

Antonio Migliarese assumes interim President role
Dr. Melissa Palmer appointed interim Chief Medical Officer
Dr. Salah Kivlighn joins CytoDyn as clinical and strategic advisor

VANCOUVER, Washington, May 24, 2023 (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 Dr. Cyrus Arman, the Company's President, has taken a medical leave of absence. During Dr. Arman's absence, Antonio Migliarese, the Company's Chief Financial Officer, will assume interim President responsibilities. Mr. Migliarese will be supported by the Company's recently appointed interim Chief Medical Officer, Dr. Melissa Palmer, as well as Dr. Salah Kivlighn, who recently joined the Company as a clinical and strategic advisor, in collectively leading the Company's continued priorities of lifting the clinical hold on the use of leronlimab in the HIV population, advancing the development of the NASH phase 2b clinical trial for submission to the FDA, and exploring potential strategic business opportunities. The Company plans to host an investment community webcast on a to-be-announced date in the near future.

Dr. Palmer is an experienced industry executive and internationally renowned Hepatologist. She has held leadership positions at various biotech and pharmaceutical companies, including CMO of Gannex/Ascletis and Head of Liver Disease Clinical Development at Takeda Pharmaceutical Company. At both Shire plc (acquired by Takeda in 2019) and Kadmon Corporation (acquired by Sanofi Company in 2021), Dr. Palmer led the global development of NASH and other liver disease programs. She was previously a clinical professor at NYU Langone Medical Center and the director of Hepatology at NYU Plainview, NY. Earlier in her career, Dr. Palmer maintained a solo medical practice devoted to treating patients with liver disease for 20 years. Since 1991, Dr. Palmer has served as a hepatology consultant to more than 60 biotech and pharmaceutical companies and has been a primary investigator for numerous clinical trials in NASH and other liver diseases. Dr. Palmer has authored over 100 publications, abstracts, manuscripts, and book chapters, in addition to the best-selling book "Dr. Melissa Palmer's Guide to Hepatitis and Liver Disease." Dr. Palmer, either as the primary author or co-author with colleagues from the FDA, has published several guidelines concerning drug-induced liver injury among patients in clinical trials evaluating potential drugs to treat NASH and other liver diseases. She trained in Hepatology at Mount Sinai School of Medicine, where she also received her M.D. degree. She received her Bachelor of Science degree from Columbia University in New York City.

Dr. Kivlighn, who is currently President and Managing Member of The Kivlighn Group, LLC, a company that provides strategic consulting services to companies across the biotech and pharmaceutical industry, brings to the Company more than 30 years of industry experience. Having held both scientific and commercial leadership roles, Dr. Kivlighn is a rare blend of science and business acumen. Recently, Dr. Kivlighn served as CEO of HepaTx

Corporation, providing strategic, financial, and operational leadership. Prior to HepaTx, Dr. Kivlighn served as the Senior Vice President of Global Strategic Marketing and Program Operations for United States Pharmacopeia (“USP”), the official pharmacopeia for the United States. At USP, he created a new division with members in China, India, Europe, Latin America, and APAC, delivering a revitalized sales and marketing culture that yielded an average compound annual growth rate of 8.6%. Before his tenure at USP, he served as Commercial Vice President of Kite Pharma, Inc., now a subsidiary of Gilead Sciences. As Global Product Development Team Lead at MedImmune, Inc., a subsidiary of AstraZeneca, Dr. Kivlighn and his team spearheaded the development of a Leukemia drug, LUMOXITI® (moxetumomab pasudotox) which was acquired by INNATE Pharma, an independent clinical-stage biotech company. He also serves in advisory and board member roles for several companies.

Dr. Kivlighn began his career at Merck & Co. (“Merck”) where he held positions of increasing responsibility during his 15-year tenure. While at Merck, Dr. Kivlighn was the lead scientist for the discovery and development of Cozaar® (losartan), and later helped to lead the massive growth of Cozaar® to $3.5B in worldwide revenue. As a scientist and marketer, Dr. Kivlighn contributed to the successful launch of a number of trials. At Merck, he also co-led the development and commercialization of RotaTeq® leading to an $800M franchise; RotaTeq® was awarded universal recommendation by the Advisory Committee on Immunization Practices. Among Dr. Kivlighn’s many accolades, his team earned the prestigious Prix Galien Award for Best Biotechnology Product for RotaTeq®. In addition, he earned the AstraZeneca CEO Award for his leadership during the development of LUMOXITI® (moxetumomab pasudotox). Dr. Kivlighn is a sought-after global speaker and thought leader and has authored more than 77 peer-reviewed scientific publications. He holds a Ph.D. in Pharmacology from Texas Medical Center (University of Houston, Baylor College of Medicine & University of Texas Medical School), completing a fellowship in Integrated Physiology under the esteemed advisors Arthur C. Guyton and Thomas Lohmeier at the University of Mississippi Medical Center, and a Bachelor of Science in Distributed Studies from Iowa State University.

Dr. Palmer said, "I am excited about joining CytoDyn to support the further development of leronlimab following its impressive phase 2 data in patients with NASH. I am eager to help accelerate the NASH clinical development program and look forward to working with the Company's talented team and Dr. Kivlighn, with whom I’ve had the pleasure of working in the past.” Dr. Kivlighn stated, “I have had the pleasure of getting to know the Company’s Board of Directors and Tanya, Cyrus and Antonio, in addition to gaining an understanding of leronlimab, the current status of its development programs, the potential it has in various indications, and the current objectives related to the HIV clinical hold and future NASH clinical trial. I am thrilled to be able to leverage my experience and knowledge of the Company to support Antonio and the Company’s clinical, regulatory, and strategic efforts during Dr. Arman’s leave of absence.” Tanya Urbach, Board Chair, said “Given the unanticipated circumstances, we are blessed to have had such a talented CMO as Dr. Palmer recently join the Company. We are further grateful for Dr. Kivlighn’s willingness to step in and support Antonio and the team at this time. Dr. Palmer and Dr. Kivlighn each bring significant experience not only in the oncology and NASH spaces but also in leadership roles with clinical and drug development companies. I believe these two individuals, coupled with Antonio’s strong management abilities, will allow us to not miss a beat during Cyrus’s absence.”

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 may include statements about leronlimab, its ability to provide positive health outcomes, the Company's ability to resolve the clinical hold imposed by the FDA, the Company's ability to develop a successful operating strategy and thereby create shareholder value, the ability to obtain regulatory approval of the Company's drug products 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 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 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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