



NEWS RELEASE

# Coya Therapeutics (“Coya”) Announces the Appointment of Dr. Merit Cudkowicz, M.D., M.Sc., as Clinical Advisor to Support the Development of COYA 302 for the Treatment of Amyotrophic Lateral Sclerosis (ALS)

7/19/2023

- Dr. Merit Cudkowicz is the Director of the Sean M. Healey & AMG Center for ALS, Chief of Neurology at Mass General, Director and the Julieanne Dorn Professor of Neurology at Harvard Medical School.
- Dr. Cudkowicz’s research and clinical activities are dedicated to the study and treatment of people with ALS; she is one of the founders and past Co-Chairs of the Northeast ALS Consortium (NEALS), a group of over 134 clinical sites in the United States, Canada, Europe and the Middle East dedicated to performing collaborative clinical trials and research in ALS.
- Dr. Cudkowicz will support the development of Coya’s most advanced clinical asset, COYA 302, a dual-mechanism investigational biologic combination comprised of low dose Interleukin-2 (ld-IL2) that is intended to enhance anti-inflammatory regulatory T cell function with a fusion protein (CTLA4-Ig) that is intended to suppress pro-inflammatory cell function.
- Coya previously reported positive clinical data for COYA 302 for the treatment of ALS in a four-patient, open-label investigator-initiated trial illustrating that treatment with LD-IL2 + CTLA4-Ig halted disease progression over 6 months, and resulted in minimal decline over 12 months, in a cohort of patients who were declining prior to study initiation at an average of -1.1 ALSFRS-R points per month.

HOUSTON--(BUSINESS WIRE)-- Coya Therapeutics, Inc. (NASDAQ: COYA) (“Coya” or the “Company”), a clinical-stage biotechnology company developing biologics intended to enhance Treg function, today announced the engagement

of Merit Cudkowicz, MD, MSc as expert clinical advisor. Dr. Cudkowicz is a world-renowned neurologist who has dedicated her career to improving the life of patients with ALS and other serious neurological conditions. Dr. Cudkowicz brings decades of experience supporting the development of new therapies for ALS.

Dr. Cudkowicz is Principal Investigator of the Clinical Coordination Center for the National Institute of Neurological Disorders and Stroke's Neurology Network of Excellence in Clinical Trials (NeuroNEXT). Dr. Cudkowicz has launched the first platform trial initiative in ALS, the HEALEY ALS Platform Trial, a program that helps accelerate therapy development in ALS.

Dr. Cudkowicz received the American Academy of Neurology 2009 Sheila Essay ALS award, the 2017 Forbes Norris Award from the International MND Alliance, the 2017 Pinnacle Award from the Boston Chamber of Commerce and the 2019 Ray Adams American Neurological Association Award. A dedicated educator, Dr. Cudkowicz mentors many young neurologists in clinical investigation of ALS and related neurodegenerative disorders. Dr. Cudkowicz completed her undergraduate degree in chemical engineering at Massachusetts Institute of Technology and obtained a medical degree in the Health Science and Technology program of Harvard Medical School. She served her internship at Beth Israel Hospital in New York and her neurology residency and fellowship at Massachusetts General Hospital. She also obtained a master's degree in Clinical Epidemiology from the Harvard School of Public Health.

Dr. Merit Cudkowicz commented: "I am happy to join Coya as a clinical advisor as they move COYA 302 into a well powered and designed clinical trial. COYA 302's dual mechanism of action in enhancing Treg function and dampening other pro-inflammatory pathways combined with their early clinical proof of concept data provides strong rationale to move forward as a therapeutic strategy in ALS."

"We are privileged to leverage Dr. Cudkowicz's expertise in supporting our clinical plans to rapidly advance COYA 302 in patients with ALS," added Fred Grossman, D.O., Coya's President and Chief Medical Officer.

## About Coya Therapeutics, Inc.

Headquartered in Houston, TX, Coya Therapeutics, Inc. (Nasdaq: COYA) is a clinical-stage biotechnology company developing proprietary treatments focused on the biology and potential therapeutic advantages of regulatory T cells ("Tregs") to target systemic inflammation and neuroinflammation. Dysfunctional Tregs underlie numerous conditions including neurodegenerative, metabolic, and autoimmune diseases, and this cellular dysfunction may lead to a sustained inflammation and oxidative stress resulting in lack of homeostasis of the immune system. Coya's investigational product candidate pipeline leverages multiple therapeutic modalities aimed at restoring the anti-inflammatory and immunomodulatory functions of Tregs. Coya's lead therapeutic programs includes Treg-enhancing biologics (COYA 300 Series product candidates) COYA 301 and COYA 302, which are intended to enhance

Treg function and expand Treg numbers. COYA 301 is a cytokine biologic for subcutaneous administration intended to enhance Treg function and expand Treg numbers in vivo, and COYA 302 is a biologic combination for subcutaneous and/or intravenous administration intended to enhance Treg function while depleting T effector function and activated macrophages. These two mechanisms may be additive or synergistic in suppressing inflammation. For more information about Coya, please visit [www.coyatherapeutics.com](http://www.coyatherapeutics.com)

## Forward-Looking Statements

This press release contains “forward-looking” statements that are based on our management’s beliefs and assumptions and on information currently available to management. Forward-looking statements include all statements other than statements of historical fact contained in this presentation, including information concerning our current and future financial performance, business plans and objectives, current and future clinical and preclinical development activities, timing and success of our ongoing and planned clinical trials and related data, the timing of announcements, updates and results of our clinical trials and related data, our ability to obtain and maintain regulatory approval, the potential therapeutic benefits and economic value of our product candidates, competitive position, industry environment and potential market opportunities. The words “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect,” and similar expressions are intended to identify forward-looking statements.

Forward-looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors including, but not limited to, those related to risks associated with the impact of COVID-19; the success, cost and timing of our product candidate development activities and ongoing and planned clinical trials; our plans to develop and commercialize targeted therapeutics; the progress of patient enrollment and dosing in our preclinical or clinical trials; the ability of our product candidates to achieve applicable endpoints in the clinical trials; the safety profile of our product candidates; the potential for data from our clinical trials to support a marketing application, as well as the timing of these events; our ability to obtain funding for our operations; development and commercialization of our product candidates; the timing of and our ability to obtain and maintain regulatory approvals; the rate and degree of market acceptance and clinical utility of our product candidates; the size and growth potential of the markets for our product candidates, and our ability to serve those markets; our commercialization, marketing and manufacturing capabilities and strategy; future agreements with third parties in connection with the commercialization of our product candidates; our expectations regarding our ability to obtain and maintain intellectual property protection; our dependence on third party manufacturers; the success of competing therapies or products that are or may become available; our ability to attract and retain key scientific or management personnel; our ability to identify additional product candidates with significant commercial potential consistent with our commercial objectives; ; and our estimates regarding expenses, future revenue, capital requirements and needs for additional financing.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. Moreover, we operate in a very competitive and rapidly changing environment, and new risks may emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed herein may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Although our management believes that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances described in the forward-looking statements will be achieved or occur. We undertake no obligation to publicly update any forward-looking statements, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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