NEWS RELEASE

Coya Therapeutics Launches the ALSTARS Trial, a Phase 2 Clinical Study to Assess the Efficacy and Safety of COYA 302 in Amyotrophic Lateral Sclerosis

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The ALSTARS Trial is a well powered randomized, multi-center, double-blind, placebo-controlled, 24-week study of COYA 302 in people with Amyotrophic Lateral Sclerosis (ALS)

Patients completing the initial 24-week treatment will be invited to participate in a 24-week blinded extension period, during which all participants will receive COYA 302

The ALSTARS Trial will enroll 120 ALS participants at approximately 25 centers in the United States and Canada

HOUSTON, Sept. 22, 2025 /PRNewswire/ -- Coya Therapeutics, Inc. (NASDAQ: COYA) ("Coya" or the "Company"), a clinical-stage biotechnology company focused on developing biologics that enhance regulatory T cell (Treg) function in patients with neurodegenerative disorders, announced today the launch of the ALSTARS Trial, a Phase 2, randomized, multi-center, double-blind, placebo-controlled study to evaluate the efficacy and safety of COYA 302 for the treatment of ALS (**ClinicalTrials.gov** Identifier: NCT 07161999).

Eligible study participants will be randomized to receive one of two different doses of COYA 302 or placebo in this 24-week, double-blind study. Participants who complete the initial placebo-controlled phase will be invited to enroll in an additional 24-week blinded extension to assess the long-term safety and efficacy of COYA 302. During this extension, all participants will receive COYA 302 at one of the two prespecified doses.

Study details, including eligibility criteria and current study locations, can be found **here**. Additional locations will

continue to be added. The study will be presented on September 29, 2025, during the NEALS Educational Webinar by Dr. James Berry, MD, MPH and registration can be found **here**.

Fred Grossman, Chief Medical Officer stated "The launch of the ALSTARS Trial represents a significant milestone in our mission to develop innovative therapies for patients with ALS. We believe COYA 302's unique mechanism of enhancing regulatory T cell number and function offers a promising new approach towards developing a potential therapy for this devastating disease with high unmet medical need. We look forward to evaluating its potential to meaningfully impact the lives of ALS patients and their families."

About COYA 302

COYA 302 is an investigational and proprietary biologic combination therapy with a dual immunomodulatory mechanism of action intended to enhance the anti-inflammatory function of regulatory T cells (Tregs) and suppress the inflammation produced by activated monocytes and macrophages. COYA 302 comprises proprietary low dose interleukin-2 (LD IL-2) and CTLA-4 Ig and is being developed for subcutaneous administration for the treatment of patients with ALS. These mechanisms may have additive or synergistic effects.

COYA 302 is an investigational product not yet approved by the FDA or any other regulatory agency.

About Amyotrophic Lateral Sclerosis

Amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's Disease, is a rare neurological disease that affects motor neurons, the nerve cells in the brain and spinal cord that control voluntary muscle movement. About 20,000 people live with ALS in the United States and approximately 5,000 new cases are diagnosed every year. The disease is progressive, meaning the symptoms get worse over time. The functional status of ALS patents declines about 1 point per month on average, as measured by the Revised ALS Function Rating Scale1, or ALSFRS-R, a validated tool to monitor the progression of the disease. ALS has no cure, and the currently approved drug treatments provide limited benefit to patients. ALS is a type of motor neuron disease. As motor neurons degenerate and die, they stop sending messages to the muscles, which causes the muscles to weaken, start to twitch (fasciculations), and waste away (atrophy). Eventually, the brain loses its ability to initiate and control voluntary movements. Most people with ALS die from respiratory failure, usually within three to five years from when the symptoms first appear.2

Atassi N, et al. The PRO-ACT database: design, initial analyses, and predictive features. Neurology, 2014;83:1719–1725. doi: 10.1212/WNL.0000000000000951.
National Institutes of Health (NIH) Website (**https://www.ninds.nih.gov/health-information/disorders/amyotrophic-lateral-sclerosis-als**), accessed on January 4, 2023.

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. This cellular dysfunction may lead to 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 therapeutic platforms include Treg-enhancing biologics, Treg-derived exosomes, and autologous Treg cell therapy.

For more information about Coya, please visit **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 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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