



NEWS RELEASE

Coya Therapeutics Announces Completion of Full Enrollment in Phase 2/3 ALSTARS Trial of COYA 302 for the Treatment of ALS

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120th participant has been enrolled in ALSTARS trial achieving target enrollment

Additional eligible participants already in active screening will be allowed to enroll

Topline data from 24-week double-blind treatment phase on track for early Q2 2027

HOUSTON--(BUSINESS WIRE)-- Coya Therapeutics, Inc. (NASDAQ: COYA) ("Coya" or the "Company"), a clinical-stage biotechnology company developing biologics intended to enhance T-cell (Treg) function in patients with neurodegenerative disorders, today announced full enrollment of the planned 120 participants in the Company's Phase 2/3 ALSTARS Trial (NCT07161999) evaluating COYA 302, Coya's combination of proprietary low-dose IL-2 and CTLA-4 Ig, for the potential treatment of amyotrophic lateral sclerosis (ALS). Additional participants already engaged in active screening will be allowed to enroll in the trial if deemed eligible. Topline data from the double-blind treatment phase are anticipated in early Q2 2027.

"Having achieved the planned enrollment, ALSTARS has reached an important milestone as we advance toward the first randomized, placebo-controlled efficacy data for COYA 302 in ALS," said Arun Swaminathan, Ph.D., Chief Executive Officer of Coya. "We believe this study will provide important insights into whether our dual immunomodulatory approach can potentially slow disease progression in people living with ALS. We remain focused on rigorous execution of this trial and look forward to the topline readout in early Q2 2027."

“We are pleased with the continued progress of the COYA 302 ALS program and our collaboration with Coya,” said Erez Israeli, Chief Executive Officer, at Dr. Reddy’s Laboratories Ltd. “We look forward to completion of the ALSTARS trial and, if approved by regulatory agencies, bringing this novel treatment option to patients and their families impacted by ALS.”

Coya and Dr. Reddy’s Laboratories entered into an exclusive collaboration in December 2023 for the development and commercialization of COYA 302 for the treatment of ALS. Under the agreement, Dr. Reddy’s obtained exclusive commercialization rights to COYA 302 for ALS globally with the exception of Japan, South America and Mexico, while Coya is responsible for advancing clinical development and seeking regulatory approval of COYA 302 for ALS in the United States.

COYA 302 has received FDA Fast Track designation for the treatment of ALS. Fast Track designation is intended to facilitate the development and expedite the review of drugs that treat serious conditions and address unmet medical needs.

About Amyotrophic Lateral Sclerosis (ALS)

ALS is a progressive neurodegenerative disease characterized by the degeneration of motor neurons in the brain and spinal cord that control voluntary muscle movements, including those required for speaking, swallowing, and breathing.

The disease progresses rapidly, with patients experiencing an average decline of approximately one point per month on the ALS Functional Rating Scale-Revised (ALSFRS-R), and 20% to 30% of patients dying within two years of diagnosis despite available therapies. Approximately 90% of ALS cases are sporadic, occurring in people with no known family history of the disease. Current approved therapies provide only a modest clinical effect and may slow, but do not stop disease progression and functional decline, highlighting the significant unmet need for new treatment options that can meaningfully alter the course of the disease.

About the ALSTARS Trial

The ALSTARS Trial is a Phase 2/3, randomized, multicenter, double-blind, placebo-controlled study designed to evaluate the efficacy and safety of COYA 302 in patients with ALS. Approximately 120 participants will be randomized 1:1:1 to receive one of two pre-specified dosing regimens of COYA 302 or placebo during a 24-week double-blind treatment phase. Patients who complete the 24-week placebo-controlled phase enter a 24-week blinded active-treatment extension phase; patients receiving COYA 302 continue their assigned regimen, while placebo patients are re-randomized to one of the two COYA 302 dosing regimens, providing up to 48 weeks of data on COYA 302.

The primary endpoint is the change in disease severity over time, measured by the Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised (ALSFRS-R) total score from baseline to Week 24 compared with placebo. Study objectives include evaluation of efficacy, safety and tolerability, biological activity, and biomarker levels.

To learn more about the study, please visit **ALSTARS Trial**.

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 and other neurodegenerative diseases. These mechanisms may have additive or synergistic effects.

Coya is currently conducting the ALSTARS Trial, a Phase 2/3, randomized, multicenter, double-blind, placebo-controlled study to evaluate the efficacy and safety of COYA 302 for the treatment of ALS (Identifier: NCT07161999).

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

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 within the meaning of the Private Securities Litigation

Reform Act of 1995. Statements in this press release that are not statements of historical fact are forward-looking statements. Such forward-looking statements include, without limitation, statements regarding: the timing of topline data from the double-blind treatment phase; expectations of Coya Therapeutics, Inc. (the “Company”) regarding the potential benefits, effectiveness and safety of its product candidates; the significance and potential benefits associated with the FDA’s Fast Track designation for COYA 302; the Company’s ability to advance its product candidates through the preclinical and clinical development processes; the Company’s expectations regarding quality, timing, and availability of data from the Company’s clinical trials; the timing of announcements, updates and results of the Company’s clinical trials and related data; the Company’s future results of operations and financial position, including cash runway; and the potential therapeutic benefits and economic value of the Company’s product candidates. These forward-looking statements are based on the beliefs of the management of the Company as well as assumptions made by and information currently available to the Company. Such statements reflect the current views of the Company with respect to future events and are subject to known and unknown risks and uncertainties. In light of these risks and uncertainties, the events or circumstances referred to in the forward-looking statements may not occur. These and other factors that may cause the Company’s actual results to differ from current expectations are discussed in the Company’s filings with the Securities and Exchange Commission (the “SEC”), including the section titled “Risk Factors” in the Company’s Annual Report on Form 10-K for the year ended December 31, 2025. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date this press release is given. Except as required by law, the Company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

Investor Contact

David Snyder, CFO

david@coyatherapeutics.com

Media Contacts

Russo Partners

David Schull

David.Schull@russopartnersllc.com

858-717-2310

Rachelle Babb

rachelle.babb@russopartnersllc.com

929-325-7559

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