



NEWS RELEASE

Coya to Initiate Open-Label Extension of Phase 2/3 ALSTARS Trial of COYA 302 in ALS

2026-10-14

- OLE planned in response to requests from ALSTARS investigators and participants
- Eligible participants completing 48 weeks of treatment will have the opportunity to continue receiving COYA 302
- Cash runway guidance remains unchanged into the second half of 2027, beyond anticipated ALSTARS topline data readout in early Q2

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 plans to initiate an open-label extension (OLE) of the Phase 2/3 ALSTARS Trial (**NCT07161999**) evaluating COYA 302 for the treatment of amyotrophic lateral sclerosis (ALS).

Coya plans to initiate the OLE in response to requests from ALSTARS investigators and study participants. The OLE will provide participants who complete the 48-week treatment period with the opportunity to continue receiving COYA 302, while enabling the collection of longer-term efficacy and safety data. Coya expects the OLE to begin in November 2026 as the first cohort completes the 48-week treatment period.

"The strong interest from investigators and participants in continuing treatment beyond the current 48-week study period underscores the importance of providing continued access to COYA 302 for eligible participants in the ALSTARS trial," said Fred Grossman, DO, FAPA, President and Chief Medical Officer of Coya. "The open-label extension will also provide an opportunity to further characterize the long-term safety, tolerability, and potential treatment effects of COYA 302 in people living with ALS. We are deeply grateful to the patients, families, and

investigators whose commitment makes this important research possible.”

Concurrent with the anticipated initiation of the OLE, Coya expects to prioritize resources toward the ongoing clinical development of COYA 302 in ALS and assuring timely completion of important near-term milestones in the ALSTARS trial. With this prioritization, the planned initiation of the Phase 2 clinical trial evaluating COYA 302 in frontotemporal dementia (FTD), previously anticipated in the second half of 2026, is now expected in 2027.

“As we continue to advance and expand the ALSTARS trial, we believe prioritizing our resources behind COYA 302 in ALS is the appropriate near-term, fiscal, and operational strategy for our Company,” said David Snyder, Chief Financial Officer of Coya.

The Company’s cash runway guidance remains unchanged, with existing cash resources expected to fund operations into the second half of 2027, beyond the anticipated ALSTARS topline data readout.

About Amyotrophic Lateral Sclerosis (ALS)

ALS is a progressive neurodegenerative disease that attacks motor neurons in the brain and spinal cord that control voluntary muscles, including those needed to speak, swallow and breathe. The disease progresses rapidly, with patients experiencing an average decline of approximately one point per month on the ALS Functional Rating Scale-Revised (ALSFRRS-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 family history of the disease. Current approved therapies provide only a modest treatment effect and slow, but do not stop, disease progression and functional decline, underscoring 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, multi-center, double-blind, placebo-controlled study designed to evaluate the efficacy and safety of COYA 302 in patients with ALS. Approximately 120 subjects 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 change in disease severity over time, measured by the Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised (ALSFRRS-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.

Participants who complete the 48-week treatment period will be eligible to enroll in an open-label extension (OLE) to continue receiving COYA 302.

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, multi-center, 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 commencement of the OLE, the commencement of the Phase 2 clinical trial evaluating COYA 302 in FTD, 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.

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Source: Coya Therapeutics, Inc.