NEWS RELEASE

Coya Therapeutics to Present Neurofilament Light Chain (NfL) Biomarker Stratification Methodology in the ALSTARS Trial to Minimize the Impact of Heterogeneity in ALS Clinical Trials at the 2026 Annual NEALS Meeting

2026-10-28

ALS (amyotrophic lateral sclerosis) is a life-threatening neurodegenerative disease characterized by a highly variable rate of progression among affected individuals

The Company believes implementation of a prospective stratification in the ALSTARS Trial based on baseline axonal injury burden, as measured by serum neurofilament light chain (NfL) levels, balances prognostic risk across arms, reduces baseline heterogeneity, and may improve the signal-to-noise ratio for the ALSFRS-R, the primary outcome measure

HOUSTON--(BUSINESS WIRE)-- **Coya Therapeutics, Inc.** (NASDAQ: COYA) ("Coya" or the "Company"), a clinical-stage biotechnology company developing biologics intended to enhance Treg function, announces a poster presentation at the 2026 Annual NEALS Meeting on October 28th in Clearwater, Florida. NEALS (Network of Excellence for ALS) is the world's largest ALS research consortium, dedicated to accelerating the development of new treatments for ALS and Motor Neuron Disease (MND).

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 (ClinicalTrials.gov ID: **NCT07161999**).

The poster describes a stratification methodology based on baseline NfL serum levels designed to mitigate the impact of ALS disease progression heterogeneity in interventional clinical trials. NfL is a structural protein component of the cytoskeleton found in neurons, particularly the axon, which is released into extracellular fluids (cerebrospinal fluid and blood) when neurons are damaged. Higher NfL levels are associated with faster clinical decline, as measured by the Revised ALS Functional Rating Scale (ALSFRS-R), and shorter survival. The baseline NfL levels from eligible individuals participating in the ALSTARS Trial were grouped into three tiers - low, medium and high - allowing for a prospective stratification and balanced randomization across treatment arms. Coya believes this stratification strategy strengthens the evaluation of the COYA 302 treatment effect, independent of chance cohort imbalances.

Details of the poster presentation:

Title: Mitigating Clinical Heterogeneity in ALS Trials: The Biological Rationale and Statistical Impact of 3-Tiered Neurofilament Light (NfL) Stratification in the ALSTARS Trial

Presenter/Authors: Tyrell J. Simkins, DO, PhD*, Fred Grossman, DO, Karen King, MS, Stanley Appel, MD, and James D. Berry, MD, MPH (*Presenting author)

Poster Session 1: October 28th, 2026, 4:30-6:30 PM ET

Poster Location: Opal Sands, Ballroom

Poster Number: 7

Following the presentation, a copy of the poster will be available **here**.

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 (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 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 were 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, as 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.

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 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

Source: Coya Therapeutics, Inc.