NEWS RELEASE

Coya Therapeutics Announces Publication Demonstrating Correlation Between Longitudinal Biomarker Data and Clinical Outcomes Supporting the Mechanistic Rationale for COYA 302 in Patients with ALS

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The study evaluated serum biomarkers of lipid peroxidation, systemic inflammation, and axonal integrity in 100 randomly selected patients with ALS and included 100 healthy controls to allow for a meaningful comparison

Levels of 4-hydroxy-2-nonenal (4-HNE), lipopolysaccharide binding protein (LBP), and neurofilament light chain (NfL) at diagnosis were significantly correlated with length of survival in patients with ALS

In a previously reported Investigator Initiated Trial that studied the combination of subcutaneous low-dose interleukin 2 (LD IL-2) and CTLA-4 Ig, these biomarkers of survival were reduced from baseline

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 the publication of a research study led by Dr. David Beers and Dr. Stanley Appel at the Houston Methodist Neurological Institute. The study included the longitudinal measurement of well-characterized serum biomarkers of lipid peroxidation (4-hydroxy-2-nonenal [4-HNE]), systemic inflammation (lipopolysaccharide binding protein [LBP]), and axonal injury (neurofilament light chain [NfL]), and the functional evaluation over time of 100 randomly selected patients with ALS. The study has been published in the peer-reviewed journal Annals of Clinical and Translational Neurology and can be accessed **here**.

“These findings demonstrate significant correlations between biomarkers of inflammation, oxidative stress, and axonal injury and survival in patients with ALS”, said Dr. Fred Grossman, President and Chief Medical Officer of Coya. “In our ongoing ALSTARS trial, we are measuring NfL as a secondary endpoint, along with inflammation markers including 4-HNE and ox-LDL as exploratory endpoints. Together, these efforts will further inform the growing body of evidence supporting the role of inflammation in neurodegenerative diseases.”

Summary of Study Results

This study used longitudinal serum samples collected between January 2018 to December 2022. A cohort of 100 patients with sporadic or familial ALS was randomly selected and assayed by ELISAs for levels of 4-HNE, LBP, and NfL. A group of 100 age- and sex-matched healthy people were used as controls for the levels of biomarkers.

All three biomarkers were increased in ALS patients compared to controls. 4-HNE and LBP were increased at ALS diagnosis and continued to increase as disease progressed and both biomarkers correlated with disease progression rates and survival. NfL was increased at diagnosis and exhibited a more limited increase over time. Levels of 4-HNE, LBP, and NfL at ALS diagnosis were significantly correlated with length of survival ($p < 0.001$ for 4-HNE and LBP; $p = 0.001$ for NfL). Similarly, levels of 4-HNE and LBP were significantly correlated with the rate of disease progression ($p < 0.001$) as measured by ALSFRS-R.

The biomarker data from this longitudinal research study are consistent with the previously **reported** findings of an academic clinical study of low-dose interleukin 2 (LD IL-2) and CTLA-4 Ig in four patients with ALS. The subcutaneous administration of the active components of COYA 302 (LD IL-2 and CTLA-4 Ig) led to the reduction of biomarkers of inflammation and lipid peroxidation and resulted in a significant and durable increase of regulatory T cell (Treg) anti-inflammatory function. Clinically, the ALS patients in this study did not exhibit functional decline over the 48-week treatment period, as measured by the validated ALSFRS-R assessment tool. The mean (±SD) ALSFRS-R scores at week 24 (33.75 ±3.3) and week 48 (32 ±7.8) after initiation of treatment with LD IL-2 and CTLA-4 Ig were not statistically different compared to the ALSFRS-R score at baseline (33.5 ±5.9), indicating significant potential amelioration in the progression of the disease over the treatment period.

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**.

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 there is no currently approved treatment to arrest its progression. 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

References

1. Atassi N, et al. The PRO-ACT database: design, initial analyses, and predictive features. Neurology. 2014;83:1719–1725. doi: 10.1212/WNL.0000000000000951.
2. National Institutes of Health (NIH) Website (**https://www.ninds.nih.gov/health-information/disorders/amyotrophic-lateral-sclerosis-als**), accessed on March 24, 2026.

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, 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).

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

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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