



## NEWS RELEASE

# Coya Therapeutics Announces Results of Investigator-Initiated Study of LD IL-2 and CTLA4-Ig Demonstrating Treg Enhancement and Cognitive Stability in Frontotemporal Dementia Patients

2026-01-08

Robust target engagement was observed, with statistically significant increases in regulatory T-cell (Treg) suppressive function and Treg numbers beginning as early as two weeks post-dosing and sustained through the 22-week treatment period.

Cognitive measures remained stable, with no evidence of cognitive decline or meaningful change from baseline in either the Montreal Cognitive Assessment (MoCA) or the CDR-FTLD scores over 22 weeks.

HOUSTON--(BUSINESS WIRE)-- **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, today announced positive results of an investigator-initiated proof of concept open-label study with low-dose IL-2 and CTLA4-Ig combination treatment in 9 patients with Frontotemporal Dementia (FTD) over a 6 month period. The study was led by Dr. Alireza Faridar and Dr. Stanley Appel at the Houston Methodist Neurological Institute (Houston, TX) with funding from The Peggy and Gary Edwards Endowment Fund. Study patients received subcutaneously administered CTLA4-Ig, along with a 5-day course of low-dose IL-2 every four weeks, for a total of 22 weeks of dosing and follow-up. The study enrolled 9 patients, and data demonstrated enhanced Treg numbers and function and cognitive function stability as measured by CDR-FTLD and Montreal Cognitive Assessment (MOCA).

Dr. Arun Swaminathan, Coya's Chief Executive Officer followed: "We believe these results suggest the potential for COYA 302 as a therapeutic option for patients with FTD. We look forward to advancing COYA 302 in a well-controlled phase 2 clinical trial in patients with FTD."

Dr. Fred Grossman, Coya's Chief Medical Officer said: "We believe this study continues to add evidence that restoring Treg numbers and function has the potential to translate to clinically meaningful effects across multiple neurodegenerative diseases."

## Study Results

The data presentation can be found in this [LINK](#)

### Safety and feasibility

Nine individuals clinically diagnosed with FTD were enrolled into this study. The primary endpoints were the incidence and severity of adverse events. The most common adverse event was erythema at the injection site (33.3% of individuals), which was mild and recovered spontaneously. No serious adverse events were observed during the study.

### Treg Suppression

Treg suppressive function was significantly increased starting as early as 2 weeks after dosing and remained significantly amplified throughout the 22-week treatment period.

Treg Percentage followed a similar pattern as Treg suppressive function, with significant separation from baseline occurring as early as 2 weeks post dosing and remained significantly elevated through week 22.

CD25 mean fluorescence intensity (MFI) was significantly increased as early as 2 weeks after dosing and remained significantly elevated through 22 weeks.

FOXP3 MFI was significantly increased as early as 2 weeks after dosing.

### Cognitive Measures

MOCA (Montreal Cognitive Assessment) scores remained unchanged at week 22, compared to baseline (Baseline, 13.5 and week 22, 14) suggesting no decline in cognitive function over the 22-week period.

CDR-FTLD scores did not significantly change at week 22 compared to baseline levels (Baseline, 4.8 and week 22,

5.5), suggesting no decline in cognitive and functional status of the enrolled individuals over the 22-week treatment period.

## 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.

## 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 <https://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; anticipated interactions with the FDA under Fast Track designation; 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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Source: Coya Therapeutics, Inc.