



NEWS RELEASE

Coya Therapeutics Announces Completion of Patient Enrollment of an Investigator-Initiated, Open-Label Study with Low-Dose IL-2 and CTLA4-Ig Combination Treatment in Patients with Mild to Moderate Frontotemporal Dementia

2025-09-29

Following the positive interim results in 5 patients announced earlier this year, a total of 9 patients have been enrolled as planned

The study is progressing according to protocol, and no safety issues have been reported

Study completion is anticipated in Q4 2025 with topline to follow

HOUSTON, Sept. 29, 2025 /PRNewswire/ -- 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, announces completion of patient enrollment of an investigator-initiated, proof-of-concept, open-label study with low-dose IL-2 and CTLA4-Ig combination treatment in patients with Frontotemporal Dementia (FTD). The study is 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, followed by a 5-day course of low-dose IL-2 every four weeks, for a total of 22 weeks of dosing and follow-up.

Following the positive interim results of 5 patients announced in April 2025, the study has enrolled an additional 4

patients for a total of 9 FTD patients. The trial is progressing according to the study protocol and no serious adverse events or discontinuations due to safety issues have been reported. Study completion is anticipated in Q4 2025 with topline to follow. Following database lock and analysis of the data, the Company plans to release the results of the study.

"We are pleased to announce the completion of this important clinical milestone. FTD is a devastating neurodegenerative disease of high unmet need. We remain committed to developing an effective and safe treatment for this rare form of dementia," Dr. Fred Grossman, CMO commented.

About Frontotemporal Dementia

Frontotemporal dementia (FTD) refers to a group of neurodegenerative disorders characterized by altered behavior and language, with a progressive decline in executive function.¹ FTD affects an estimated 30,000 Americans.² FTD is categorized clinically into various subtypes; the main three include behavioral-variant frontotemporal dementia and two language variants, semantic dementia (also known as semantic variant primary progressive aphasia) and progressive non-fluent aphasia (also known as non-fluent variant primary progressive aphasia). FTD is a presenile dementia, meaning it can occur in younger individuals, often between the ages of 45 and 64. The average age of onset is 58, with an average survival time of 7.5 years.^{1,2}

References

Knopman et al. Development of methodology for conducting clinical trials in frontotemporal lobar degeneration. *Brain* 2008; 131(11): 2957-2968.

Rascovsky et al. Rate of progression differs in frontotemporal dementia and Alzheimer disease. *Neurology* 2005; 65(3): 397-403.

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 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 impact of COVID-19; 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; 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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