



## NEWS RELEASE

# Coya Therapeutics Announces Positive Interim Results of an Investigator-Initiated Open Label Study with Low-Dose IL-2 and CTLA4-Ig Combination Treatment in Five Patients with Mild to Moderate Frontotemporal Dementia

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- Results from the first patient cohort (N=5) of an open-label proof of concept academic study with low-dose IL-2 and CTLA4-Ig demonstrated a rapid and durable statistically significant increase in the number and suppressive function of Tregs compared to baseline values.
- Clinically, patients with Frontotemporal Dementia (FTD) demonstrated minimal to no cognitive decline throughout the study period. Treatment was well tolerated, no serious adverse events were reported, and all 5 patients completed the study.

HOUSTON--(BUSINESS WIRE)-- Coya Therapeutics, Inc. (NASDAQ: COYA) ("Coya" or the "Company"), a clinical-stage biotechnology company developing biologics intended to enhance regulatory T cell (Treg) function announced positive interim results 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. The study aims to enroll up to 10 patients, and these interim results include data from the first 5 patients with mild to moderate FTD who have completed the full course of treatment.

Dr. Arun Swaminathan, Coya's Chief Executive Officer followed: "The results thus far are consistent with previously published encouraging data from an open-label investigator-initiated study of patients with ALS treated with low-dose IL-2/CTLA4-Ig. This interim data in FTD provides us further confidence of our approach to target and enhance Treg biology to address devastating neurodegenerative diseases including ALS and FTD."

Previous biomarker data presented by the Company demonstrated that FTD patients exhibit a compromised immunosuppressive function of regulatory T cells (Tregs), along with increased peripheral levels of inflammatory cytokines and chemokines, dysregulation of monocytes, and systemic activation of the inflammatory cascade, supporting the critical role of the immune system in the pathophysiology of FTD.

One previous study showed that a cohort of 68 patients with FTD worsened by an average of 3.57 points over a 12-month period per the Clinical Dementia Rating - Frontotemporal Lobar Degeneration (CDR-FTLD) scale (Knopman et al. Brain 2008; 131(11): 2957-2968). In addition, patients with FTD typically have shorter survival times and more rapid rates of cognitive and functional decline compared to patients with Alzheimer's disease (Rascovsky et al. Neurology 2005; 65(3): 397-403).

Dr. Fred Grossman, Coya's Chief Medical Officer stated: "We are excited with the results observed in this initial group of patients with this proof-of-concept study. We believe that the increase in Treg numbers and suppressive function, with subsequent anti-inflammatory biological activity still to be evaluated, underscores the potential for this low-dose IL-2/CTLA4-Ig combination to be further studied as a therapy for FTD, for which there are no currently approved treatments."

## Summary of Interim Study Results

Overall, treatment with low-dose IL-2 and CTLA4-Ig was well tolerated. All 5 patients enrolled in the first cohort completed the study and received the investigational treatment as planned. The most common adverse events were mild injection site reactions. No serious adverse events were reported.

Treg numbers and suppressive function increased after the first treatment cycle ( $p < 0.01$  and  $p < 0.05$ , respectively), and remained at higher significant levels throughout the treatment period.

Clinical functional assessments were performed in all patients at pre-specified timepoints over the course of the study using validated tools, including the Clinical Dementia Rating - Frontotemporal Lobar Degeneration (CDR-FTLD) scale, the Montreal Cognitive Assessment (MoCA) scale, and the Progressive Aphasia Severity Scale (PASS). Results of the functional tests show that, on average, these five FTD patients treated with low-dose IL-2 and CTLA4-Ig combination exhibited minimal to no cognitive decline over the course of the study, compared to pre-treatment values.

The Company intends to publish and/or present more comprehensive data in a future peer-reviewed meeting and/or publication.

## 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.<sup>1</sup> FTD affects an estimated 30,000 Americans.<sup>2</sup> 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). It's 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.<sup>1,2</sup>

### References

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

COYA 302 is a combination treatment comprised of low-dose IL-2 and CTLA4-Ig is an investigational therapy with a dual immunomodulatory mechanism of action intended to enhance the anti-inflammatory function of Tregs and suppress the inflammation produced by activated monocytes and macrophages. Coya is developing COYA 302 for the treatment of fatal neurodegenerative diseases characterized by chronic inflammation and Treg dysfunction.

For more information about Coya, please visit [www.coyatherapeutics.com](http://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 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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