NEWS RELEASE

Coya Therapeutics' COYA 301 Increased Treg Function and Halted Cognitive Decline in an Open Label Study in Patients with Alzheimer's Disease

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- The open-label study evaluated the safety and tolerability, biological activity, blood biomarkers and preliminary efficacy of COYA 301 in 8 patients with Alzheimer's disease (AD). The investigator-initiated study was conducted by Dr. Appel and Dr. Faridar at the Houston Methodist Hospital.
- COYA 301 is Coya's investigational low-dose interleukin-2 (IL-2) for subcutaneous administration. COYA 301 has been designed to enhance the function of regulatory T cells (Tregs) in vivo.
- Treatment with COYA 301 resulted in a statistically significant improvement in cognitive function, as measured by the Mini-Mental State Examination test (MMSE). In addition, no cognitive decline was observed when it was measured by the Alzheimer's Disease Assessment Scale–Cognitive Subscale (ADAS-Cog), and the Clinical Dementia Rating-Sum of Boxes scale (CDR-SB).
- Treatment with COYA 301 appeared to be well tolerated in patients with AD.
- Over the course of the study, COYA 301 restored peripheral Treg function and numbers, and lowered the levels of systemic pro-inflammatory chemokines and biomarkers in patients with AD.

HOUSTON--(BUSINESS WIRE)-- **Coya Therapeutics, Inc.** (NASDAQ: COYA) ("Coya" or the "Company"), a clinical-stage biotechnology company developing multiple therapeutic platforms intended to enhance Treg function, including biologics and cell therapies, today reported results from an open-label proof-of-concept clinical study for COYA 301 in patients with AD. Results of the study will be presented on May 16, 2023, at the Keystone Conference 'Neurodegeneration: New Biology Guiding the Next Generation of Therapeutic Development' in Whistler, B.C. Canada. The poster can be accessed **here**.

The study enrolled 8 patients with confirmed presence of brain amyloid pathology and baseline MMSE scores between 12 and 25. The patients were treated with five-day-courses of COYA 301 for four monthly cycles and were followed for two months post-treatment. Treg function and numbers, serum biomarkers of inflammation, and cognitive functioning as measured by the ADAS-Cog, CDR-SB and MMSE assessment tools were evaluated.

Clinically, evaluation of cognitive function showed that administration of COYA 301 resulted in a statistically significant improvement in mean MMSE scores during the treatment phase, compared to mean MMSE score at baseline (p=0.015). Consistent with the positive trend in MMSE score, mean scores in ADAS-Cog and CDR-SB scales did not significantly change at the end of treatment with COYA 301, compared to pre-treatment baseline scores, indicating no cognitive decline as measured by these validated instruments.

During the 4-month treatment period, COYA 301 appeared to be well tolerated. The most common adverse events were mild injection-site reactions and mild leukopenia. No serious adverse events were reported, and no patient discontinued the study.

COYA 301 administration significantly expanded Treg population and function. At baseline, the mean (SD) percentage of Tregs was 4.55 (1.97) and was almost double at the end of the treatment [8.68 (2.99), p=0.0004]. Mean (SD) Treg suppressive function was 46.61% (7.74) at baseline, and significantly increased to 79.5 % (20.55) at the end of treatment (p=0.003). In addition, COYA 301 significantly lowered the blood levels of the pro-inflammatory cytokines and chemokines IL-15, CCL2 and CCL11 following each treatment cycle.

Chemokines are among the next generation AD Biomarkers and are important regulators of both the central and peripheral immune response and play a critical role in inflammatory processes of the brain. Many studies have found that chemokines regulate the infiltration of peripheral immune cells into the AD brain, are involved in the accumulation of Aβ deposition in microglia cells and tau phosphorylation, and correlate with disease progression and survival. Modulating chemokines and other pro-inflammatory markers with treatments in AD may serve as potential indicators of disease progression and therapeutic response.

Stanley Appel, M.D., Professor at Houston Methodist and Chair of Coya's Scientific Advisory Board commented, "Our study of low-dose IL-2 in patients with AD provided promising results. The therapy was well tolerated, and most significantly it demonstrated expansion in Treg population, and lowered pro-inflammatory cytokines and chemokines. These positive findings were further supported by lack of decline in cognitive function during the treatment phase, suggesting that low dose IL-2 may provide a potentially meaningful approach for the treatment of AD."

"We believe the outcomes of this proof-of-concept study of COYA 301 in patients with AD are encouraging and we will continue to analyze the data to decide our next steps. These results and the recent positive data for COYA 302

in the treatment of ALS strengthen Coya's approach for the development of immunotherapies for the treatment of neurodegenerative diseases," Adrian Hepner, M.D., Ph.D., President and Chief Medical Officer of Coya commented.

Additional details about the study can be found at **www.coyatherapeutics.com**

About Alzheimer's Disease

Alzheimer's disease is the most common cause of dementia, a general term for memory loss and other cognitive abilities serious enough to interfere with daily life. Alzheimer's disease accounts for up to 80% of dementia cases, affecting an estimated 5.7 million Americans. In more than 90% of people with Alzheimer's, symptoms do not appear until after age 60. The incidence of the disease increases with age and doubles every 5 years beyond age 65. Alzheimer's is a progressive disease, where dementia symptoms gradually worsen over a number of years. In its early stages, memory loss is mild, but with late-stage Alzheimer's, individuals lose the ability to carry on a conversation and respond to their environment. It is the sixth leading cause of death among all adults and the fifth leading cause for those aged 65 or older. On average, a person with Alzheimer's lives 4 to 8 years after diagnosis but can live as long as 20 years, depending on other factors. 1,2

References

1. Alzheimer's Association (**www.alz.org**).
2. Centers for Disease Control and Prevention (**www.cdc.gov**).

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 a 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's 300 Series product candidates, COYA 301 and COYA 302, are biologic therapies intended to enhance Treg function and expand Treg numbers. COYA 301 is a cytokine biologic for subcutaneous administration intended to enhance Treg function and expand Treg numbers in vivo, and COYA 302 is a biologic combination for subcutaneous and/or intravenous administration intended to enhance Treg function while depleting T effector function and activated macrophages. These two mechanisms may be additive or synergistic in suppressing inflammation. 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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