



NEWS RELEASE

Coya Therapeutics, Inc. Announces Preclinical Data Supporting the Role of Expanded Regulatory T Cells (Tregs) as Potential Disease-Modifying Treatment in an Animal Model of Alzheimer's Disease (AD)

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- Administration of expanded human Tregs with amplified immunomodulatory function suppressed neuroinflammation and alleviated AD pathology in a mice model of AD.
- Expanded human Tregs reduced amyloid burden and downregulated neuroinflammatory markers in the brain including pro-inflammatory cytokines, complement cascade, toll like receptors, and microglia.
- Data provide preclinical support for Treg enhancing therapies as a potential treatment strategy in AD and other neurodegenerative diseases.
- Initiation of Phase I clinical trials for Treg enhancing biologics in neurodegenerative diseases expected in 2023 with interim data readout by or before Q1 2024.

HOUSTON--(BUSINESS WIRE)-- **Coya Therapeutics, Inc.** (NASDAQ: COYA) ("Coya" or the "Company"), a clinical-stage biotechnology company developing multiple therapeutic platforms that enhance Treg function, including biologics and cell therapies, announced the recent publication of an article entitled "Ex vivo expanded human regulatory T cells modify neuroinflammation in a preclinical model of Alzheimer's Disease" in the peer reviewed journal *Acta Neuropathologica Communications*. The preclinical study was conducted by Ali Faridar, M.D., of Houston Methodist Hospital (Houston, Texas), under the leadership of Stanley Appel, M.D., the chair of Coya's Scientific Advisory Board.

"These data further support that enhancing Treg function is a potential strategy to ameliorate neuroinflammation, which may modify Alzheimer's Disease-associated pathology in the brain. Coya intends to enter a Phase I clinical trial of Treg enhancing biologics for the treatment of neurodegenerative diseases in 2023 with interim data readout

anticipated by or before Q1 2024,” stated Howard Berman, Ph.D., Chief Executive Officer of Coya. “We continue advancing our product candidate pipeline including our biologic programs, which are intended to enhance Treg function in vivo and we believe have the potential to address the significant unmet needs of patients with serious neurodegenerative diseases,” stated Dr. Berman.

Stanley Appel, MD., Professor, Houston Methodist Hospital and Chair of Coya’s Scientific Advisory Board, commented, “Dr. Faridar’s transgenic mouse model study provides compelling evidence for the neuroprotective role of Tregs in suppressing neuroinflammation to improve disease pathophysiology and supports the potential role of immunomodulatory therapy for patients with AD and other neurodegenerative diseases.”

The study investigated the therapeutic effects of ex vivo expanded human Tregs on 5xFAD immunodeficient mice (5xFAD-Rag2KO), a well characterized model of AD. Treg administration reduced the levels of both soluble and insoluble A β 40 and A β 42 in the dentate gyrus and frontal cortex of treated animals compared to controls. Furthermore, Treg-treated mice showed significant reduction in total and plaque-associated microglia as well as reactive astrocytes in dentate gyrus and frontal cortex versus untreated mice.

Consistent with these findings, proteomic evaluation of the neuroinflammation transcriptome revealed that Treg administration down regulated multiple inflammatory pathways that have been observed to be associated with toxic amyloid beta (A β) including pro-inflammatory cytokines (IL1A&B, IL6), complement cascade (C1qa, C1qb, C4a/b), toll like receptors (Tlr3, Tlr4 and Tlr7) and microglial activations markers (CD14, Tyrobp, Trem2). The reduction in the number of plaque-associated glial cells and suppression of pro-inflammatory signaling pathways within these cells following Treg therapy may attenuate the contribution of these toxic glial cells in AD pathology resulting in mitigation of amyloid burden.

The peer reviewed publication can be accessed at

<https://actaneurocomms.biomedcentral.com/articles/10.1186/s40478-022-01447-z>

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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