

# Coya Therapeutics Presents New Experimental Data Supporting the Mechanism of Action of COYA 302 for the Treatment of Amyotrophic Lateral Sclerosis (ALS) at the 22nd Annual Northeast ALS (NEALS) Consortium Meeting

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- COYA 302 is an investigational and proprietary biologic combination 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 is comprised of 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;
- The experimental data generated in cell samples from ALS patients highlight the significant positive effect of LD IL-2/CTLA4-Ig and other Treg-enhancing therapies in reducing the inflammatory environment observed in ALS. It is known that the degree of neuroinflammation directly correlates with the severity and rate of progression observed in ALS;
- Coya is actively planning its next clinical study to evaluate the efficacy and safety of COYA 302 in patients with ALS.

HOUSTON--(BUSINESS WIRE)-- **Coya Therapeutics, Inc.** (Nasdaq: COYA) ("Coya" or the "Company"), a clinical-stage biotechnology company developing biologics and cell therapies intended to enhance the function of Tregs, announced new experimental data presented at the 22nd Annual Northeast ALS (NEALS) Consortium Meeting on October 4th, 2023. Details of the study can be found [here](#).

Results of the in vitro study in samples from ALS patients highlight the deleterious role of M1 pro-inflammatory

monocytes and macrophages in the ability of Tregs to maintain their immunomodulatory anti-inflammatory function and achieve immune homeostasis. Tregs are often dysfunctional in ALS, exhibiting low anti-inflammatory suppressive function. The degree of impaired Treg function has been shown to directly correlate with the severity and rate of progression of this life-threatening disease.

Prior studies conducted by Dr. Appel and his team at the Houston Methodist Hospital demonstrated that dysfunctional Tregs from ALS patients can be successfully expanded ex vivo restoring their suppressive function, but when Tregs were infused back to the patients the anti-inflammatory function had limited duration. Subsequent studies have identified that the inflammatory environment created by myeloid cells could be a key contributor to the loss of Treg suppressive function.

The present in vitro research work studied the interactions between expanded Tregs and activated monocytes and macrophages, and the ability of immunomodulatory drugs and other Treg-enhancing therapies to increase Treg anti-inflammatory function and suppress the pro-inflammatory function of the M1 phenotype of activated monocytes and macrophages.

Main results of the study are summarized below:

- M1 activated monocytes and macrophages reduce Treg viability and upregulate apoptosis markers.
- Immunomodulatory drugs known to suppress the M1 phenotype significantly decreased the production of inflammatory cytokines involved in tissue damage.
- The combination of LD IL-2/CTLA4-Ig significantly decreased the M1 phenotype and cytokine production and maintained Treg viability.

Results of this study further support the potential of COYA 302 (LD IL-2 and CTLA4-Ig) to address the multiple pathways involved in the progression and severity of ALS. Coya is working expeditiously in the planning and execution of its next clinical study to evaluate the efficacy and safety of COYA 302 in patients with ALS.

## 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 lead therapeutic programs includes Treg-

enhancing biologics (COYA 300 Series product candidates) COYA 301 and COYA 302, which are intended to enhance Treg function and expand Treg numbers. COYA 301 is a proprietary investigational recombinant human low dose IL-2 biologic for subcutaneous administration intended to enhance Treg function and expand Treg numbers in vivo, and COYA 302 is a dual-mechanism investigational biologic combination comprised of proprietary low dose IL-2 and CTLA-4 Ig. The low dose IL-2 is intended to enhance anti-inflammatory regulatory T cell function and numbers while the fusion protein CTLA-4 Ig is intended to suppress pro-inflammatory cell function. These two mechanisms may be additive or synergistic in suppressing inflammation. 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 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.

## Investor Contact

David Snyder

**david@coyatherapeutics.com**

## Hayden IR

James Carbonara

646-755-7412

**James@haydenir.com**

## Media Contact

Anna Marie Imbordino

**annamarie@quantum-corp.com**

917-680-8765

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