NEWS RELEASE

Coya Therapeutics Presents Biomarker Data on Neuroinflammatory Pathways in Frontotemporal Dementia (FTD) at the AD/PD 2024 Conference

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Regulatory T cell (Treg) immunomodulatory function significantly compromised and inflammatory cytokines and chemokines significantly increased in FTD patients

COYA 302, Coya's lead investigational product, is believed to restore Treg immunomodulatory function and target the inflammatory milieu observed in neurodegenerative diseases like FTD

HOUSTON--(BUSINESS WIRE)-- **Coya Therapeutics, Inc.** ("Coya" or the "Company"), a clinical-stage biotechnology company developing biologics primarily focused on the restoration of regulatory T cell (Treg) immunomodulatory function, announces the presentation of data demonstrating the role of the peripheral immune system in the pathophysiology of Frontotemporal Dementia (FTD) from a biomarker study conducted at the Houston Methodist Hospital by Dr. Stanley Appel and Dr. Alireza Faridar and funded by the Houston Methodist Clinical Scholar Award Program. The poster presentation was shared for the first time today at the AD/PD 2024 Conference in Lisbon, Portugal and can be found **here**. The poster is titled, "Deciphering the Role of the Peripheral Immune System in the Pathology of Frontotemporal Dementia."

"The data from this biomarker study clearly depicts a compromised peripheral immune environment present in patients with FTD that, we believe, contributes to the pathophysiology of the disease process. Further, we believe that targeting systemic inflammation with COYA 302 may lower both peripheral and central nervous system inflammatory cell types while enhancing Treg function and may be a meaningful approach for FTD. We intend to file an Investigational New Drug (IND) application with the FDA for COYA 302 in FTD later this year and initiate a Ph. 2

trial in FTD patients shortly thereafter," stated Fred Grossman, Chief Medical Officer at Coya Therapeutics.

Summary of Study Results

The study was designed to evaluate Treg immunosuppressive function, monocyte mRNA expression, levels of inflammatory cytokines and chemokines, and immune cell markers in peripheral blood mononuclear cells (PBMCs) in blood samples of 22 FTD patients and 11 age-matched healthy individuals as a control group.

Treg Function Compromised: Treg suppressive function was significantly reduced in FTD, compared to controls ($p<0.01$), demonstrating that Treg immunomodulatory function is negatively impacted in FTD.

Pro-Inflammatory Systemic Immune Activity: Plasma levels of inflammatory chemokines and cytokines, including C-X-C motif chemokine ligand 9 (CXCL9), CXCL10, CXCL11, CXCL12, tumor necrosis factor alpha (TNFα), chemokine (C-C motif) ligand 3 (CCL3), CCL7, and colony stimulating factor 1 (CSF-1) were consistently and significantly increased in FTD patients ($p<0.05$). In addition, several inflammation transcripts in monocyte genes known to be involved in neuroinflammatory signaling pathways were dysregulated in FTD, compared to controls.

Results of the study demonstrate that FTD patients exhibit a compromised immunosuppressive function of Tregs, along with increased peripheral levels of inflammatory cytokines and chemokines, dysregulation of peripheral monocyte's inflammation transcriptome and systemic activation of the inflammatory cascade, supporting the critical role of the immune system in the pathophysiology of FTD. The data in FTD is consistent the Treg dysfunction and increased levels of inflammatory cytokines and chemokines previously reported by Coya in other serious and progressive neurodegenerative diseases and support the multi-pathway combination approach of COYA 302 to target numerous components of the dysfunctional immune system.

About COYA 302

COYA 302 is an investigational and proprietary biologic combination therapy 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, FTD, and PD. These mechanisms may have additive or synergistic effects.

In February of 2023, Coya announced results from a proof-of-concept, open-label clinical study evaluating commercially available LD IL-2 and CTLA-4 Ig in a small cohort of patients with ALS conducted at the Houston Methodist Research Institute (Houston, Texas) by Stanley Appel, M.D., Jason Thonhoff, M.D., Ph.D., and David Beers, Ph.D. This study was the first-of-its-kind evaluating this dual-mechanism immunotherapy for the treatment of ALS.

Patients in the study received investigational treatment for 48 consecutive weeks and were evaluated for safety and tolerability, Treg function, serum biomarkers of oxidative stress and inflammation, and clinical functioning as measured by the ALSFRS-R scale.

During the 48-week treatment period, the therapy was well tolerated. The most common adverse event was mild injection-site reactions. No patient discontinued the study, and no deaths or other serious adverse events were reported.

Patients' disease progression was measured using the ALSFRS-R scale, a validated rating tool for monitoring the progression of disability in patients with ALS. The mean (±SD) ALSFRS-R scores at week 24 (33.75 ±3.3) and week 48 (32 ±7.8) after initiation of treatment were not statistically different compared to the ALSFRS-R score at baseline (33.5 ±5.9), suggesting significant amelioration in the progression of the disease over the 48-week treatment period.

Treg suppressive function, expressed as percentage of inhibition of proinflammatory T cell proliferation, showed a statistically significant increase over the course of the treatment period and was significantly reduced at the end of the 8-week washout post-treatment period. Treg suppressive function at 24 weeks (79.9 ±9.6) and 48 weeks (89.5 ±4.1) were significantly higher compared to baseline (62.1 ±8.1) ($p<0.01$), suggesting enhanced and durable Treg suppressive function over the course of treatment. In contrast, Treg suppressive function (mean ±SD) was significantly decreased at the end of the 8-week washout period compared to end-of-treatment at week 48 (70.3 ±8.1 vs. 89.5 ±4.1, $p <0.05$).

The study also evaluated serum biomarkers of inflammation, oxidative stress, and lipid peroxides. The available data up to 16 weeks after initiation of treatment suggest a decrease in these biomarker levels, which is consistent with the observed enhancement of Treg function. The evaluation of the full biomarker data is ongoing.

COYA 302 is an investigational product not yet approved by the FDA or any other regulatory agency.

About Amyotrophic Lateral Sclerosis

Amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's Disease, is a rare neurological disease that affects motor neurons, the nerve cells in the brain and spinal cord that control voluntary muscle movement. About 20,000 people live with ALS in the United States and approximately 5,000 new cases are diagnosed every year. The disease is progressive, meaning the symptoms get worse over time. The functional status of ALS patients declines about 1 point per month on average, as measured by the Revised ALS Function Rating Scale1, or ALSFRS-R, a validated tool to monitor the progression of the disease.

ALS has no cure, and the currently approved drug treatments provide limited benefit to patients. ALS is a type of

motor neuron disease. As motor neurons degenerate and die, they stop sending messages to the muscles, which causes the muscles to weaken, start to twitch (fasciculations), and waste away (atrophy). Eventually, the brain loses its ability to initiate and control voluntary movements. Most people with ALS die from respiratory failure, usually within three to five years from when the symptoms first appear.2

About Frontotemporal Dementia

Frontotemporal dementia (FTD) is the result of damage to neurons in the frontal and temporal lobes of the brain. Many possible symptoms can result, including unusual behaviors, emotional problems, trouble communicating, difficulty with work, or difficulty with walking. FTD is rare and tends to occur at a younger age than other forms of dementia. About 60% of people with FTD are 45 to 64 years old. FTD is progressive, meaning symptoms get worse over time. In the early stages, people may have just one symptom. As the disease progresses, other symptoms appear as more parts of the brain are affected. It is difficult to predict how long someone with FTD will live. Some people live more than 10 years after diagnosis, while others live less than two years after they are diagnosed. There is no cure for FTD, and no treatments slow or stop the progression of the disease.3

References

1. Atassi N, et al. The PRO-ACT database: design, initial analyses, and predictive features. Neurology, 2014;83:1719–1725. doi: 10.1212/WNL.0000000000000951.
2. National Institutes of Health (NIH) Website (**https://www.ninds.nih.gov**), accessed on January 8, 2024.
3. National Institutes of Health (NIH) Website (**https://www.nia.nih.gov**), accessed on January 8, 2024.

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 – the Company's lead biologic investigational product or "Pipeline in a Product"– is a proprietary combination of COYA 301 (Coya's proprietary LD IL-2) and CTLA4-Ig for subcutaneous administration with a unique dual mechanism of action that is now being developed for the treatment of Amyotrophic Lateral Sclerosis,

Frontotemporal Dementia, Parkinson's Disease, and Alzheimer's Disease. Its multi-targeted approach enhances the number and anti-inflammatory function of Tregs and simultaneously lowers the expression of activated microglia and the secretion of pro-inflammatory mediators. This synergistic mechanism may lead to the re-establishment of immune balance and amelioration of inflammation in a sustained and durable manner that may not be achieved by either low-dose IL-2 or CTLA4-Ig alone.

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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