

Coya Therapeutics (Coya) Announces Completion of Enrollment in a Well-Controlled Phase 2 Study of Low Dose Interleukin-2 (LD IL-2) in Patients with Alzheimer's Disease (AD)

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- The double-blind, placebo-controlled study (funded by the Gates Foundation and Alzheimer's Association) evaluates the safety and tolerability, biological activity, biomarkers, neuroimaging, and preliminary efficacy of LD IL-2 in 38 patients with mild-to-moderate AD over 30 weeks;
- Previously reported data from an open-label, proof-of-concept study in 8 AD patients illustrated that treatment with LD IL-2 resulted in a statistically significant improvement in cognitive function, as measured by the Mini-Mental State Examination test (MMSE) and no cognitive decline was observed as measured by the AD Assessment Scale–Cognitive Subscale (ADAS-Cog), and the Clinical Dementia Rating-Sum of Boxes scale (CDR-SB);
- Dr. Guillaume Dorothée, Ph.D., Member of Coya's Scientific Advisory Board, was among the first to illustrate the role of Regulatory T cells (Tregs) in AD and the therapeutic effects of LD IL-2 in modifying AD pathology and restoring cognitive function in animal models of AD;
- Coya's proprietary investigational LD IL-2 (COYA 301) for subcutaneous administration has been designed to enhance the function of Tregs in vivo and is being developed as a monotherapy for the treatment of AD and in combination with CTLA4 Ig (COYA 302) for the treatment of Amyotrophic Lateral Sclerosis (ALS).

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 announced completion of enrollment in a randomized, double-blind, placebo-

controlled phase 2 study of LD IL-2 in patients with mild-to-moderate AD. The study is being conducted by Drs. Stanley Appel and Alireza Faridar at the Houston Methodist Hospital.

A total of 38 patients were randomly assigned to receive subcutaneous LD IL-2 at two different dosing regimens, or matching placebo, over 21 weeks. The first patient cohort was randomized to receive LD IL-2 for 5 consecutive days every 4 weeks and the second cohort was randomized to receive LD IL-2 for 5 consecutive days every 2 weeks.

This phase 2 well-controlled study will evaluate the safety and tolerability, biological activity, blood and cerebrospinal fluid biomarkers, neuroimaging, and changes in cognitive function of LD IL-2 compared to placebo at pre-specified timepoints over the course of the 21-week treatment period and at 9 weeks after the last dose of study treatment.

Topline results of the study are anticipated to be reported in Summer 2024. The study is funded by the Gates Foundation and the Alzheimer's Association.

Coya previously reported that the treatment with LD IL-2 significantly expanded Treg population and function in an open-label proof-of concept study in 8 patients with AD. 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, evaluation of cognitive function showed that administration of LD IL-2 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 LD IL-2, compared to pre-treatment baseline scores, indicating no cognitive decline as measured by these validated instruments. Overall, administration of LD IL-2 appeared to be well tolerated in the 8 patients in the open-label, proof-of concept study. 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.

Howard Berman, Ph.D., CEO of Coya Therapeutics, stated, "We believe that a positive efficacy signal in this well powered AD trial will support advancing development of this potential therapy in Alzheimer's Disease and will lead to further study as monotherapy and in combination with recently approved treatments."

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.

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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