



NEWS RELEASE

Coya Therapeutics Announces U.S. FDA Acceptance of Investigational New Drug (IND) Application for COYA 302 for the Treatment of Frontotemporal Dementia (FTD)

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HOUSTON--(BUSINESS WIRE)-- **Coya Therapeutics, Inc.** (NASDAQ: COYA) ("Coya" or the "Company"), a clinical-stage biotechnology company focused on developing biologics that enhance regulatory T cell (Treg) function in patients with neurodegenerative disorders, announces that the U.S. Food and Drug Administration (FDA) has accepted the Company's IND for COYA 302 for the treatment of frontotemporal dementia (FTD).

FTD is the most common form of dementia in people under the age of 65, affecting about 60,000 Americans. The average age of onset is 58, with an average survival time of 7.5 years. FTD is characterized by loss of intellectual functions, such as memory problems, impaired abstract thinking, reasoning, and executive function, that are severe enough to hamper activities of daily living. The clinical manifestations include behavior changes, dietary changes, loss of empathy, apathy, and executive function. FTD constitutes a high unmet medical need, as there is no treatment to stop or ameliorate the progression of the disease.

Dr. Adam Boxer, Professor of Neurology at UCSF and a noted FTD clinical trials expert, said, "There is a great need to develop disease modifying treatments for patients with FTD since none exist today. I am pleased to see this new treatment approach with a strong scientific rationale being moved forward toward a clinical trial for sporadic FTD. I commend Coya for advancing COYA 302 into well-controlled clinical trials for these patients."

Dr. Fred Grossman, Chief Medical Officer at Coya said, "There is growing evidence for the relationship between

neuroinflammation and progression of FTD. We believe the dual mechanism of COYA 302, which is designed to enhance the anti-inflammatory function of Tregs, provides a strong scientific rationale for evaluating this therapy in patients with FTD.”

Coya expects to announce topline results from the previously announced investigator-initiated open-label study evaluating low-dose IL-2 and CTLA4-Ig in patients with mild-to-moderate FTD in the coming weeks.

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 comprises 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, and other neurodegenerative diseases. These mechanisms may have additive or synergistic effects.

Coya is currently conducting the ALSTARS Trial, a Phase 2, randomized, multi-center, double-blind, placebo-controlled study to evaluate the efficacy and safety of COYA 302 for the treatment of ALS ([ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/NCT07161999) Identifier: NCT 07161999).

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

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. 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.

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 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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