



NEWS RELEASE

Coya Therapeutics Receives Clinical Trial Application (CTA) Acceptance from Health Canada to Proceed with the COYA 302 ALSTARS Trial for the Treatment of Amyotrophic Lateral Sclerosis (ALS)

2025-12-23

The CTA No Objection Letter from Health Canada allows for initiation of patient enrollment in the ALSTARS Trial at Canadian ALS centers.

The ALSTARS Trial is a phase 2, placebo-controlled study that includes clinical sites in the United States and Canada to evaluate the efficacy and safety of COYA 302 for the treatment of ALS

The ALSTARS Trial is underway in the United States and will now proceed in Canada

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 Health Canada has accepted, without objection, the Clinical Trial Application (CTA) for COYA 302 for the treatment of amyotrophic lateral sclerosis (ALS). The CTA acceptance by Health Canada allows for activation of clinical sites in Canada, enhancing patient recruitment alongside the U.S. clinical sites.

Dr. Fred Grossman, Coya's Chief Medical Officer, commented: "The activation of Canadian sites is an important step forward for the ALSTARS Trial that we believe will further enhance recruitment of this important study currently underway in the United States. We look forward to working with the Canadian ALS centers, with the goal of potentially delivering new, safe and effective treatments for ALS."

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/study/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 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, CFO

david@coyatherapeutics.com

astr partners

Matthew Beck

matthew.beck@astrpartners.com

917-415-1750

Media Contacts

Russo Partners

Olipriya Das

Olipriya.Das@russopartnersllc.com

646-942-5588

Matthew Purcell

matthew.purcell@russopartnersllc.com

646-942-5595

Source: Coya Therapeutics, Inc.