NEWS RELEASE

Coya Therapeutics Has Been Granted U.S. FDA Fast Track Designation for COYA 302 for the Treatment of Amyotrophic Lateral Sclerosis (ALS)

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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, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for COYA 302, a proprietary investigational biologic combination therapy with a dual mechanism of action, for the treatment of amyotrophic lateral sclerosis (ALS).

The FDA Fast Track Designation is a program designed to facilitate and expedite the development and review of drugs and biologics intended to treat serious or life-threatening conditions. Its primary purpose is to ensure that promising new therapies reach patients as quickly as possible through several key regulatory advantages, which include more frequent FDA interactions, potential for rolling review, and eligibility for expedited programs such as Accelerated Approval and Priority Review.

"We are pleased to announce that COYA 302 has received FDA Fast Track designation for the treatment of ALS," said Arun Swaminathan, Ph.D., Chief Executive Officer of Coya. "This recognition underscores the devastating nature of ALS and the urgent need for new therapies. At Coya, we remain fully committed to advancing our lead biologic candidate, COYA 302, through the regulatory process with the ultimate goal of delivering—pending FDA approval—a safe and effective treatment for patients living with ALS and their families."

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. 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** 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 within the meaning of the Private Securities Litigation Reform Act of 1995. Statements in this press release that are not statements of historical fact are forward-looking statements. Such forward-looking statements include, without limitation, statements regarding: expectations of Coya Therapeutics, Inc. (the "Company") regarding the potential benefits, effectiveness and safety of its product candidates; the significance and potential benefits associated with the FDA's Fast Track designation for COYA 302; the Company's ability to advance its product candidates through the preclinical and clinical development processes; the Company's expectations regarding, quality, timing and availability of data from the Company's clinical trials; the timing of announcements, updates and results of the Company's clinical trials and related data; the Company's future results of operations and financial position, including cash runway; and the potential therapeutic benefits

and economic value of the Company's product candidates. These forward-looking statements are based on the beliefs of the management of the Company as well as assumptions made by and information currently available to the Company. Such statements reflect the current views of the Company with respect to future events and are subject to known and unknown risks and uncertainties. In light of these risks and uncertainties, the events or circumstances referred to in the forward-looking statements may not occur. These and other factors that may cause the Company's actual results to differ from current expectations are discussed in the Company's filings with the Securities and Exchange Commission (the "SEC"), including the section titled "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2025. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date this press release is given. Except as required by law, the Company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

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