NEWS RELEASE

# Coya Therapeutics Announces Successful Completion of Pre-IND Meeting with FDA on COYA101 for the Treatment of Amyotrophic Lateral Sclerosis

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Plans to submit an IND to support a Phase 2b clinical trial for COYA101

HOUSTON, Nov. 16, 2021 (GLOBE NEWSWIRE) — Coya Therapeutics, Inc. (“Coya”), a privately held clinical-stage biotechnology company developing first-in-class approaches utilizing autologous regulatory T cells (Treg) and Treg-derived exosome therapeutics for neurodegenerative and autoimmune diseases, today announced that it held a Type B Pre-Investigational New Drug (IND) meeting with the U.S. Food and Drug Administration (FDA) regarding COYA101, and received a positive response supporting the planned clinical development strategy. The objective of the meeting was to facilitate early regulatory communication and guidance through the IND submission process. COYA101, the Company’s lead investigational drug, is an autologous, expanded Treg cell therapy in development for the treatment of amyotrophic lateral sclerosis (ALS).

“We appreciate and value the FDA’s thoughtful and meaningful response, which guides the path forward for COYA101, a first-in-class cell therapy intended to modulate the oxidative stress and neuroinflammation observed in ALS and other neurodegenerative conditions,” said Howard Berman, Ph.D., Chief Executive Officer of Coya Therapeutics. “We remain encouraged by the extensive preclinical data and promising clinical data from the two investigator-initiated Phase 1 and 2a trials conducted at the Houston Methodist Hospital and Massachusetts General Hospital. Building on this, we will continue to work with the FDA in a collaborative and productive manner to advance COYA101 as efficiently as possible. By harnessing the neuroprotective effects of Treg cell therapy, this important step brings us closer to potentially transforming the treatment landscape for patients with serious neurodegenerative and autoimmune diseases of high unmet medical need.”

Coya expects to file an IND in the second half of 2022 and anticipates initiating a well powered and controlled Phase 2b clinical trial shortly after.

About Coya Therapeutics, Inc.
Headquartered in Houston, TX, Coya Therapeutics™ is a clinical-stage biotechnology company developing first-in-class and best-in-class approaches utilizing adoptive regulatory T cells (Tregs) to target disease. The company's CTreg™ (Cryopreservation for Tregs) system is patent pending and the first in the industry to overcome prior limitations of Treg cell therapies, allowing for serial infusions from a single manufacturing run. Coya's proprietary TAI™ (Tregs Against Inflammation™) involves the conversion of millions of dysfunctional Tregs into billions of "Super Tregs", with superior immunosuppressive functionality. Our patent pending iscEXO™ (immunosuppressive cell Exosome) platform is a Treg-derived exosome asset focused on the advancement of disease modifying approaches to address the significant unmet medical needs of patients with ALS, Frontotemporal Dementia, Parkinson's, Alzheimer's, and autoimmune diseases. For more information, please visit www.coyatherapeutics.com

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