NEWS RELEASE

# Coya Therapeutics Receives Orphan Drug Designation from the FDA for ALS001, an Autologus Treg Cell Therapy, for the Treatment of ALS

7/7/2021

- Completed Phase 2a trial with full data release by end of summer 2021

HOUSTON, July 07, 2021 (GLOBE NEWSWIRE) — Coya Therapeutics, Inc. (Coya), a 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 the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to ALS001, an autologous, expanded Treg cell therapy in development for the treatment of amyotrophic lateral sclerosis (ALS).

“The orphan drug designation for ALS001 underscores the medical need that exists for patients with ALS,” said Howard Berman, Ph.D., Chief Executive Officer of Coya Therapeutics. “Although there are currently no meaningful treatments for these patients, we are excited by our preclinical and early clinical data demonstrating ALS001’s ability to harness the neuro-protective effects of Treg cell therapy – ultimately slowing and halting the progression of ALS. ALS001 has completed an ongoing Phase 2a trial with topline data expected late summer 2021. We look forward to showcasing our manufacturing scalability, optimizing our clinical development plans, and working with the FDA to bring ALS001 to patients as efficiently and quickly as possible.”

ALS is a progressive neurodegenerative disease primarily affecting motor neurons in the cortex, brain stem and spinal cord. As a result, symptoms include the loss of mobility, muscle control, speech and eventually the ability to breathe. ALS pathogenesis consists of two stages: an early, slow progressive neurodegenerative stage, and later, a rapidly progressing neurotoxic stage associated with anti-inflammatory and pro-inflammatory immune responses.

Recent advancements and growing supportive research have indicated that dysfunctional and decreased levels of Treg may be key drivers of ALS progression and the neurodegenerative disease process. According to the ALS Association, approximately 5,000 people are diagnosed per year, and the average life expectancy is two to five years. Patients are in desperate need of transformative therapeutic options.

The FDA Office of Orphan Products Development grants Orphan Drug Designation to investigational treatments intended for rare diseases affecting fewer than 200,000 people in the U.S. The program was created to encourage the development of medicines for rare diseases, and benefits include tax credits and application fee waivers designed to offset some development costs, as well as eligibility for market exclusivity for seven years following approval.

About Coya Therapeutics, Inc.
Headquartered in Houston, TX, Coya Therapeutics (TM) 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 (TM) (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 round. Through our proprietary TAI™ (Tregs Against Inflammation™) and patent pending iscEXO (TM) (immunosuppressive cell Exosome) platforms, Coya is 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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