



NEWS RELEASE

Coya Therapeutics Announces Annals of Neurology Publication Featuring Biomarker Data in ALS Patients Treated with Tregs Cell Therapy

4/27/2022

HOUSTON—(**BUSINESS WIRE**)—**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 the publication of results from a Phase 1 trial entitled “Tregs Attenuate Peripheral Oxidative Stress and Acute Phase Proteins in ALS.” The paper detailing the evaluation of critical biomarkers of neuroinflammation and oxidative stress with the potential ability to select ALS patients exhibiting a greater chance of therapeutic response to Treg cell therapy (COYA 101) was published in the *Annals of Neurology*, an official journal of the American Neurological Association, and can be found [here](#).

The published study data support the proposed mechanism of action and biological activity of expanded Tregs, and these findings were consistent in a subsequent Phase 2a study in ALS patients. Importantly, the biomarker data and the observed positive clinical outcomes in a hard-to-treat condition such as ALS validates Coya’s Treg-derived exosome and biologic platforms, designed to enhance Treg suppressive function and their anti-inflammatory and immunomodulatory effects in neurologic and autoimmune diseases.

“Our laboratory has long documented that peripheral inflammatory constituents such as lipid peroxides and acute phase proteins are increased in ALS patients, with levels more markedly elevated in fast progressing patients. Our new data demonstrates that Treg Cell therapy enhances suppression of proinflammatory biomarkers and, in turn, correlates with slowing of disease progression. Thus, responsiveness of pro-inflammatory constituents to Treg immunomodulatory therapies may provide meaningful biomarkers of clinical efficacy in ALS trials,” commented

Stanley H. Appel, M.D., Chair, Stanley H. Appel Department of Neurology, Houston Methodist Hospital and Chair of Coya's Scientific Advisory Board.

"Biomarker driven patient stratification is a hallmark in oncology trials, but has lagged in neurodegenerative diseases. With this data and new findings from the phase 2a trial, we will aim to leverage oxidative stress and inflammatory biomarkers to enrich for patients who are more likely to respond to our Treg enhancing treatment modalities across our platforms," added Howard Berman, Ph.D., Chief Executive Officer of Coya Therapeutics.

Summary of Publication

Regulatory T lymphocyte (Treg) cell therapy was assessed for suppression of oxidative stress (OS) and acute phase proteins (APP) responses in longitudinal serum samples from subjects with amyotrophic lateral sclerosis (ALS) enrolled in a phase I clinical trial. The first round of ex-vivo expanded Treg cell therapy suppressed levels of oxidized low-density lipoprotein (ox-LDL).

During a six-month washout period, ox-LDL levels increased. A second round of therapy again suppressed ox-LDL levels and then rose following the cessation of treatment. Serum levels of APPs, soluble CD14, lipopolysaccharide binding protein, and C-reactive protein, were stabilized during Treg cells administrations, but rose during the washout period and again after therapy was discontinued.

Treg cell therapy has the potential to suppress peripheral OS and the accompanying circulating pro-inflammatory induced APPs, both of which may serve as peripheral candidates for monitoring clinical efficacy of immunomodulating therapies.

About Coya Therapeutics, Inc.

Headquartered in Houston, TX, Coya Therapeutics™ is a clinical-stage biotechnology company developing three therapeutic platforms to enhance regulatory T cell function to ameliorate diseases driven by systemic and neuro-inflammation: Autologous Treg cell therapeutics, Allogeneic Treg exosome modalities, and biologic combinations. The Treg cell therapy is the most clinically advanced in its class, overcoming numerous manufacturing and logistical issues of prior generation approaches resulting in the conversion of millions of dysfunctional Tregs into billions of "Super Tregs" with superior immunosuppressive functionality. The Treg-derived exosome products are allogeneic, off-the-shelf highly potent immunomodulatory assets being developed to address 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.

Contacts

Investor Contact

David Snyder

david@coyatherapeutics.com

Media Contact

Jessica Starman

media@coyatherapeutics.com

