This Company Is Focused on Treg-Enhancing Therapies - Could This Be Medicine's Next Frontier?

NEWS RELEASE BY **COYA THERAPEUTICS INC.**

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By David Willey, Benzinga

Texas-based biotech company, **Coya Therapeutics** (NASDAQ: COYA), is positioning itself as a leader in a promising area of the medical field. When the father of company CEO and founder Howard Berman was diagnosed with dementia, Berman became inspired to turn his expertise in neuroscience towards developing a treatment that could help his father and others like him. Now the company has conducted trials that show the promise of a new therapy to slow or stop neurodegenerative diseases like Parkinsons, Alzehimers, and Amyotrophic Lateral Sclerosis (ALS), as well as other autoimmune and metabolic diseases.

Cell and gene therapy (CGT) is a growing biomed market. It is currently **worth** over $18 billion and was forecasted to grow at a compound annual growth rate (CAGR) of 22.41% by Precedence Research, bringing its value to over $93 billion by 2030.

Regulatory T cell (Treg) therapy is a developing field in the cell therapy market. It has been **inspired** by the successes of Chimeric antigen receptor (CAR)-T cell therapies for treating cancer. CAR-T treatments, which engineer the immune system to respond to the cancerous cells, have seen high **complete remission rates** in cancer patients suffering from cancers like B-cell acute lymphoblastic leukemia (B-ALL).

Treg-based therapies look to apply the innovations of CAR-T therapy to other diseases. It's an exciting field, with around **$3 billion** raised by investors over the past decade. More than 180 trials for Treg therapy have been registered in the past twenty years, however the majority of these trials are still pre-clinical.

While many companies involved in Treg-based therapy remain in the pre-clinical stage, one is already bringing data to the table. Coya Therapeutics is advancing multiple Treg-based therapy modalities and is one of the most clinically advanced companies in the Treg field.

Coya Is Tackling Inflammation At Its Source

Many neurodegenerative diseases, including ALS and Parkinson's Disease, are often driven by widespread inflammation, resulting from a malfunction of Treg cells. Coya Therapeutics is investigating Treg's potential for reducing inflammation by modifying the Treg cell to make it functional again and down-regulate the cytokine inflammation.

The company believes that restoring Treg cells' functionality could either slow or stop the spread of these diseases. Unlike some others in the market, Coya has been able to bring its therapies to the clinic. With its Coya-101 therapy, it has validated this approach for cell therapy, with two trials that either slowed or stopped the disease's progression.

With its Coya 302 therapy, it is also looking to add biologics to its portfolio. In two proof of concept studies, the company has identified two biologics which treat Alzheimers and ALS, and biomarkers indicate patients seeing some recovery for the disease. Also biologic treatments, which are derived from living organisms as opposed to synthetic chemicals, have the advantage of being both cheaper and more scalable than traditional treatments. Biologics can be developed as "off the shelf" therapies, as opposed to the more time-consuming autologous treatments that are specific to each patient.

Other companies working in the TREG space include **Sonoma Biotherapeutics**, which has received investment from the venture arm of **Eli Lilly and Company** (NYSE: LLY), **GentiBio**, which has seen investment from the venture arm of **Novartis** (NYSE: NVS), and **Abata Therapeutics**.

Treg-based therapies are a unique way to target inflammation and potentially reverse the spread of the disease at the cellular level. Currently there are only two FDA-approved drugs on the market to treat ALS and Frontotemporal dementia (FTD), and they don't seem to halt the disease. While **studies** have sought to reduce inflammation in ALS patients using drugs like cyclooxygenase-2, or through **experimental therapies** that use intracerebral and intrathecal delivery, these approaches are either too invasive or don't appear to reduce inflammation. Coya believes its novel cell therapy could see positive results, just as CAR-T treatment saw cancer remission rates without the negative side effects of treatments like chemotherapy.

Want to learn more about Coya Therapeutics and its Treg therapies? **Visit its website**.

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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, and this cellular dysfunction may lead to a 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. Coya's 300 Series product candidates, COYA 301 and COYA 302, are biologic therapies intended to enhance Treg function and expand Treg numbers. COYA 301 is a cytokine biologic for subcutaneous administration intended to enhance Treg function and expand Treg numbers in vivo, and COYA 302 is a biologic combination for subcutaneous and/or intravenous administration intended to enhance Treg function while depleting T effector function and activated macrophages. These two mechanisms may be additive or synergistic in suppressing inflammation.

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