

Avotres Announces Achieving Primary Endpoint of its Phase 1/2 Clinical Trial of AVT001 in Patients with Type 1 Diabetes

- AVT001 met its primary endpoints (safety) and demonstrated a strong efficacy signal at the primary readout of its phase 1/2 study for Type 1 Diabetes

CEDAR KNOLLS, NJ, UNITED STATES, December 9, 2022 /EINPresswire.com/ -- [Avotres Inc.](#), a clinical stage biotechnology company developing transformational immune therapies for autoimmune diseases, cancers, and transplantation, announced today that they have achieved a positive primary readout in their combined phase 1/2 study ([NCT03895996](#)) for the treatment of [Type 1 Diabetes](#) (T1D) patients with AVT001.

Avotres announced positive Day 150 data from the Phase 1/2 clinical trial of AVT001, an investigational autologous dendritic cell-based vaccine, in persons within 1 year of diagnosis of T1D. This randomized (2:1 ratio of treated vs placebo), double blinded, placebo-controlled trial enrolled patients aged 16 and older (n=25). The primary endpoints of the study are safety/tolerability at day 150. The main secondary efficacy endpoint is changes from baseline in the area under the curve (AUC) of the stimulated C-peptide levels over a 4-hour mixed meal tolerance test (MMTT). The study is still ongoing with long term (2 year) follow up on safety/tolerability and efficacy expected by the end of 2023.

"The readout in the T1D trial with AVT001 are very encouraging. The excellent safety profile and significant reduction in decline in C-peptide increases confidence in this novel treatment mechanism for persons with T1D." said Jason Gaglia, MD, MMSc, Principal Investigator of the T1D trial. "We look forward to sharing detailed results from the phase 1/2 trial in 2023."

"The significance and impact of this first in vivo clinical data on me and all the people who have devoted themselves to this approach for the past three decades, is extremely rewarding, encouraging and motivational." said Dr. Hong Jiang, Chief Scientific Officer and Founder of Avotres. "It represents the final 'dot' which begins to complete the evidence chain and close the scientific loop of the Avotres science and technology, and its potential applications in medicine." Dr. Jiang emphasized, "The T1D first in human clinical trial was preceded by decades of basic research coupled with in vitro and in vivo studies on four animal models and ex-vivo studies on nearly 300 clinically diagnosed autoimmune disease patients across more than 20 distinct autoimmune diseases."

According to the Juvenile Diabetes Research Foundation (www.jdrf.org), it is estimated that some 1.45 million people have T1D in the U.S., with 64,000 people diagnosed each year. T1D management places a large burden on patients and their families with marked adverse financial consequences for society. It has therefore become imperative to develop more effective treatments for T1D.

About AVT001

AVT001 is an investigational autologous dendritic cell-based vaccine for a broad spectrum of autoimmune diseases. It specifically targets restoring the normal function of the HLA-E restricted CD8+ T cell mediated regulatory pathway to effectively re-establish peripheral self-tolerance which has been impaired in the majority of the patients suffering from a variety of autoimmune diseases. The dysfunction of this pathway is considered potentially responsible for the onset of a broad spectrum of autoimmune diseases as a common root cause.

About Avotres

Avotres Inc. is a clinical stage biotechnology company developing transformational immunotherapies for autoimmune diseases, cancers, and transplantation rejection. Targeting these therapeutic areas with high unmet medical needs, we apply cutting edge science to unveil a potentially paradigm shifting scientific conceptual framework mediated by a novel immunological regulatory pathway in the hope to transform the treatment for millions of patients. We consider it our mission to tackle these diseases from their root cause(s) and aim to reach the goal of relieving patients from the disease burden. Find out more at www.avotres.com.

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