

# AVT001 Phase I/II Clinical Trial 1 Year Data in Type 1 Diabetes is Published

*From Breakthrough Discovery to Clinical Proof of Concept*

CEDAR KNOLLS, NJ, USA, June 25, 2024 /EINPresswire.com/ -- [Avotres](#) Inc. in collaboration with Joslin Diabetes Center, a Harvard Medical School affiliate, have reported one year data of a phase I/II clinical trial of AVT001 in [type 1 diabetes](#), which provided the first human in-vivo data of a unique



innovative new therapeutic approach. In this first-in-human study, treatment with the autologous dendritic cell therapy AVT001 showed excellent safety, without dose limiting adverse events. Compared with placebo, treatment with AVT001 was associated with evidence of preservation of endogenous insulin secretion through day 360.

The study appears in the latest issue of [NEJM Evidence](#), published today. <https://evidence.nejm.org/doi/full/10.1056/EVIDoa2300238>.

Building on research from Columbia University Medical Center identifying a defect in a newly recognized T cell regulatory pathway (Q/E CD8+ Treg pathway), which normally controls autoreactive T cells that attack the body's own tissues and organs, Avotres scientists developed AVT001. In this clinical trial, it is confirmed that the majority of people with type 1 diabetes, have insufficient function of this regulatory pathway, and that this defect is correctable.

"For decades, autoimmune diseases have been treated by non-specifically reducing overall immune responses. That's been effective, to certain extend, in decreasing disease symptoms and extending life spans, but has been hard on the quality of life for many of those patients," said Hong Jiang, MD, PhD, the founder and Chief Scientific Officer at Avotres Inc.. "Now we have targeted the potential common root cause in this type 1 diabetes clinical trial by testing the specific mechanism of how the Q/E CD8+ Treg pathway functions via a process of self-nonsel discrimination in the periphery. In this clinical trial, AVT001 treatment was precisely designed, manufactured, and tested based on the exact cellular/molecular mechanism (Q/E CD8+ Treg pathway) that we have identified. AVT001 corrected the defect in this pathway, with preservation

of endogenous insulin secretion. We hope to develop innovative and novel therapies that specifically target the root cause of the disease in patients without damaging their normal ongoing immune functions”.

“This study was designed to test the safety of this approach and determine if treatment with AVT001 could alter T regulatory function in persons with type 1 diabetes, which had previously only been demonstrated in the lab. As a first in human study, it was not designed to demonstrate efficacy, however, the preservation of C-peptide noted as compared to placebo is very encouraging.” said Jason Gaglia, MD, MMSc, Principal Investigator of the trial.

The underlying scientific principles that led to the development of AVT001 are based on work by Dr. Hong Jiang and the late Drs. Leonard Chess and Benvenuto Pernis and tested in human in vivo studies of clinical trial led by Dr. Jason Gaglia. The theory known as the “Avidity Model” of peripheral T cell regulation provides the conceptual basis to selectively target and down-regulate only the T cells that are harbingers of autoimmunity without damaging the body’s normal anti-infection and anti-tumor responses.

Dr. Jiang commented: “The unique specificity of the regulation by the Q/E CD8+ Treg pathway presents a rarely seen therapeutic advantage to target a wide spectrum of autoimmune diseases and other immunologically relevant clinical conditions without the necessity to identify the disease specific pathogenic antigens, which is an extremely challenging task to accomplish.”

#### 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 Q/E CD8+ Treg 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](http://www.avotres.com).

#### Disclaimer

This media update contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be

identified by words such as “potential,” “can,” “will,” “plan,” “may,” “could,” “would,” “expect,” “anticipate,” “look forward,” “believe,” “committed,” “investigational,” “pipeline,” “launch,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved products described in this media update, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that the investigational or approved products described in this media update will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Avotres is providing the information in this media update as of this date and does not undertake any obligation to update any forward-looking statements contained in this media update as a result of new information, future events or otherwise.

Tuochuan Dong  
Avotres Inc.  
+1 716-909-3370  
[email us here](#)

---

This press release can be viewed online at: <https://www.einpresswire.com/article/722881487>

EIN Presswire's priority is source transparency. We do not allow opaque clients, and our editors try to be careful about weeding out false and misleading content. As a user, if you see something we have missed, please do bring it to our attention. Your help is welcome. EIN Presswire, Everyone's Internet News Presswire™, tries to define some of the boundaries that are reasonable in today's world. Please see our Editorial Guidelines for more information.

© 1995-2024 Newsmatics Inc. All Right Reserved.