

AION Healthspan Announces First Patient Treated in Phase I/II Clinical Trial for Cell Therapy in Chronic Kidney Disease

The clinical trial, focused on Diabetic Nephropathy and other forms of Chronic Kidney Disease, is underway at the University of Miami.

MIAMI, FL, UNITED STATES, May 19, 2025 /EINPresswire.com/ -- [AION Healthspan, Inc.](https://www.aionhealthspan.com/), a clinical-stage biotechnology company advancing regenerative medicine for degenerative diseases, today announced that the first patient has now received both infusions as part of treatment in its ongoing Phase I/II first-in-human

clinical trial of AION-301. The study, which is focused on Diabetic Nephropathy and other forms of Stage 3 Chronic Kidney Disease (CKD), is being conducted as a double-blinded, randomized, controlled trial in accordance with its FDA-authorized Investigational New Drug (IND) application.



An artistic depiction of AION Healthspan's REJUVXL Cell Therapy for Chronic Kidney Disease.

“

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Trial Milestone: First Patient Successfully Treated

The study ([NCT06721143](https://clinicaltrials.gov/ct2/show/study/NCT06721143)), now underway at the University of Miami Health System, is progressing as planned in its evaluation of safety, tolerability, and early efficacy signals of AION Healthspan's investigational cell therapy. The company announces that the first patient has successfully received both scheduled infusions, marking a significant

milestone in the ongoing clinical program.

“This is an exciting and meaningful step in advancing this cell therapy approach to treating chronic kidney disease,” said Dr. Yelena Drexler, Principal Investigator on the CKD trial. “The successful completion of the investigational infusions for our first patient demonstrates our

commitment to providing innovative therapies and paves the way for further critical observations and data collection. We are encouraged by the momentum and the support from both our patients and clinical team.”

The CKD Burden and Need for Innovation

CKD remains a growing public health crisis:

- CKD affects over 110 million people in the U.S. and Europe;
- 1 in 3 adults with diabetes suffers from Diabetic Kidney Disease;
- Current therapies may slow but rarely halt or reverse disease progression.

AION Healthspan’s investigational therapy targets inflammation and fibrosis, the core drivers of kidney damage in CKD, with the goal of preserving or restoring renal function before the disease advances to dialysis or transplant.

“With the global rise in the prevalence of kidney disease, and the associated mortality rates often worse than the rates seen in oncology, the need for regenerative, disease-modifying treatments is urgent,” said Dr. Alessia Fornoni, nephrologist and member of AION’s Scientific Advisory Board. “We believe this approach, if successful, could represent a fundamental shift for CKD management.”

About the Investigational Therapy: REJUVXL™

REJUVXL™ is a ready-to-administer cell therapy derived from perinatal tissues that are usually discarded after delivery of healthy newborn babies. A scalable, robust manufacturing platform allows production of thousands of therapeutic cell doses that can be administered through a simple intravascular infusion (similar to a blood transfusion) and do not require treatment with anti-rejection drugs (immunosuppression) for the recipients. These cell products represent the youngest source of cells that can be obtained after birth, eliminating the need for embryonic or fetal cell products, and their associated risks.

Possible mechanisms of action include:

- Reduction of inflammation and fibrosis
- Modulation of the immune system
- Promotion of angiogenesis and tissue regeneration

Optimized for chronic inflammatory and degenerative diseases, REJUVXL™ is first being evaluated for CKD, with potential expansion into additional indications.

Expanding the REJUVXL™ Pipeline

The CKD trial is a key step in AION Healthspan's broader mission to develop regenerative therapies for multiple degenerative diseases. Alongside this trial, AION Healthspan is advancing a combination therapy approach for graft-versus-host disease (GvHD), with the first patient already treated at Stanford University. These efforts reinforce AION Healthspan's commitment to pioneering transformative treatments and precision medicine approaches to restore health and extend healthspan.

About AION Healthspan, Inc.

AION Healthspan, Inc. is a clinical-stage biotechnology company dedicated to advancing regenerative medicine for acute and chronic degenerative diseases. Built on decades of pioneering cell therapy research at the Diabetes Research Institute Cell Transplant Center, University of Miami Miller School of Medicine, AION Healthspan is led by a team of world renowned scientists and industry leaders. The company's proprietary technology platform, REJUVXL™, targets inflammation, fibrosis, immunity, and aging at the cellular level. While its first clinical focus is on CKD, AION Healthspan plans to expand into additional indications.

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