

## AION Healthspan Launches First-in-Human Clinical Trial for REJUVXL™ Cell Therapy in Chronic Kidney Disease

AION Healthspan announces enrollment for its first-in-human Phase I/II clinical trial in Diabetic Nephropathy and other forms of Chronic Kidney Disease.

MIAMI, FL, UNITED STATES, March 2, 2025 /EINPresswire.com/ -- AION Healthspan, Inc., a clinical-stage biotech dedicated to advancing regenerative medicine for acute and chronic degenerative diseases, today announces the initiation of enrollment for its first-in-human Phase I/II clinical trial targeting Diabetic Nephropathy



An artistic rendering of AION Healthspan`s REJUVXL Cell Therapy for Chronic Kidney Disease.

and other forms of Chronic Kidney Disease (CKD, Stage 3).

The U.S. Food and Drug Administration (FDA) has authorized the Investigational New Drug (IND) application to proceed with the Phase I/II clinical trial, marking a key milestone in advancing AION Healthspan's proprietary REJUVXL™ cell therapy.



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Dr. Yelena Drexler, Principal Investigator on the CKD trial

## Clinical Trial Overview

The study (NCT06721143) is being conducted at the University of Miami Health System and aims to assess the safety, tolerability, and early efficacy signals of REJUVXL™ in patients with CKD. CKD affects one in three adults with diabetes (Diabetic Kidney Disease) and 38% of individuals over 65, impacting over 110 million people in the U.S. and Europe alone. If successful, this therapy could inhibit or even reverse CKD progression, potentially preventing end-

stage renal disease (ESRD), dialysis, and kidney transplantation.

Dr. Yelena Drexler, Principal Investigator on the CKD trial, stated: "If successful, REJUVXL™□ has

the potential to transform the landscape of chronic kidney disease treatment. CKD represents a significant and growing health challenge, and despite advances in care, current therapies are limited in their ability to halt or reverse disease progression. The objective of REJUVXL™□ is to target the underlying causes of CKD—chronic inflammation and fibrosis—while promoting tissue repair and regeneration. If successful, this therapy has the potential to change the course of the disease for millions of patients, reducing the need for dialysis and transplant, and ultimately improving patient outcomes and quality of life."

Chronic Kidney Disease: A Pressing Unmet Medical Need

CKD remains a major global health challenge, often progressing toward advanced stages with limited treatment options, ultimately requiring dialysis or transplantation. Current treatments delay progression but fail to prevent or reverse disease advancement, underscoring the urgent need for novel therapies. "At a time when the compound annual growth rate for kidney diseases has reached that of cancer, REJUVXL™ is uniquely positioned toward a successful clinical development", says Alessia Fornoni, MD PhD, a nephrologist and member of the Scientific Advisory Board of AION Healthspan. REJUVXL™ aims to fill this critical gap to improve kidney function and enhance patient quality of life at early stages of disease progression (CKD Stage 3), where early interventions may be more effective.

## About REJUVXL™ Cell Therapy

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 anti-rejection drugs (immunosuppression) treatment of 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

 $\hfill\square\hfill$  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 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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