



Renalytix plc
("Renalytix" or the "Company")

First use of *KidneyIntelX* in a clinical trial for new CKD therapy

Key milestone in partnered pharma programme with AION Healthspan

First patient treated in clinical trial of AION Healthspan`s novel investigational cell therapy, REJUVXL™

LONDON and NEW YORK, 20 May 2025 – Renalytix plc (LSE: RENX) (OTCQB: RNLXY), a precision medicine company with lead testing service *kidneyintelX.dkd*, the only FDA-approved and Medicare reimbursed prognostic test to support early-stage risk assessment in chronic kidney disease, announces that a key milestone has been reached in the very first use of *KidneyIntelX* in a clinical trial, following the successful enrollment and treatment of the first patient to determine the safety and efficacy of a novel cell therapy for patients with Chronic Kidney Disease ("CKD").

Renalytix and AION Healthspan, Inc, a US-based clinical-stage biotech company dedicated to advancing regenerative medicine for acute and chronic degenerative diseases, are partnering in the use of *KidneyIntelX* as a precision medicine solution in the clinical development programme for AION Healthspan`s REJUVXL™ (AION-301), including helping monitoring of therapeutic efficacy. This partnered programme represents the first instance where *KidneyIntelX* is incorporated into a clinical trial of a new therapy in CKD. Change in *KidneyIntelX* risk levels is included as an outcome measure in this first-in-human clinical trial. Under the terms of the agreement, Renalytix will be responsible for determining *KidneyIntelX* risk levels in subjects enrolled in the study and supporting analysis of the data in accordance with the clinical protocol.

The announcement from AION Healthspan can be viewed here:

<https://www.wboy.com/business/press-releases/ein-presswire/813815808/aion-healthspan-announces-first-patient-treated-in-phase-i-ii-clinical-trial-for-cell-therapy-in-chronic-kidney-disease/>

Fergus Fleming, Chief Technology Officer of Renalytix, commented: *"We are delighted to congratulate AION on meeting this very significant milestone in the development of their novel immunomodulatory and regenerative cell therapy technology targeted at CKD. If successful, this therapy will add to the growing therapeutic options for patients, further highlighting the need for the KidneyIntelX precision medicine platform to accelerate clinical development and enable optimized treatment and outcomes for patients. Renalytix is in a strong position to support pharmaceuticals companies looking to incorporate a precision medicine solution, like KidneyIntelX, into their clinical development and commercial programmes, activity which supports the increasing diversification of our revenue streams."*

Giacomo Lanzoni, Chief Scientific Officer of AION Healthspan, Inc, stated: *"We are thrilled to partner with Renalytix in our first-in-human clinical trial of REJUVXL™, and to be the first cell therapy development program to leverage KidneyIntelX for risk stratification and analyses of efficacy. Integrating this robust biomarker strategy into our protocol will deepen our understanding of patient response and safety, and accelerate our path toward truly personalized regenerative treatments for chronic kidney disease."*

Further information on AION Healthspan, REJUVXL™, and the active clinical trial can be found below:

<https://clinicaltrials.gov/study/NCT06721143/>

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) 596/2014, as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

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About Renalytix (www.renalytix.com)

Renalytix (LSE: RENX) (OTCQB: RNLXY) is an artificial intelligence-enabled *in vitro* diagnostics company, focused on optimizing clinical management of kidney disease to drive improved patient outcomes. Renalytix has received FDA approval and Medicare reimbursement for *kidneyintelX.dkd* which is now offered commercially in the United States.

Unrecognized and uncontrolled kidney disease remains one of the largest barriers to controlling cost and suffering in the United States and the United Kingdom's medical system, affecting over 14 million and 8 million people, respectively. After five years of development and clinical validation, *kidneyintelX.dkd* is the only FDA-approved and Medicare reimbursed prognostic tool capable of understanding a patient's risk with kidney disease early where treatment has maximal effect. *kidneyintelX.dkd* is now being deployed across large physician group practices and health systems in select regions of the United States.

The over 15,000 patients that have been tested by *kidneyintelX.dkd* have produced a substantial body of real-world performance data. In patient populations where *kidneyintelX.dkd* has been deployed, a demonstrated and significant increase in diagnosis, prognosis, and treatment rates have been recorded. *kidneyintelX.dkd* now has full reimbursement established by Medicare, the largest insurance payer in the United States, at \$950 per reportable result. *kidneyintelX.dkd* is also recommended for use in the international chronic kidney disease clinical guidelines (KDIGO).

KidneyIntelX is based on technology developed by Mount Sinai faculty and licensed to Renalytix AI, Inc. Mount Sinai faculty members are co-founders and equity owners in the Company. In addition, the Icahn School of Medicine at Mount Sinai has equity ownership in Renalytix.

About AION Healthspan, Inc. (www.aionhealthspan.com)

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.

AION'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.