

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

kidneyintelX.dkd data presented at ERA Congress

kidneyintelX.dkd shown to enhance risk assessment across all KDIGO categories

*Use of SGLT2i reduces kidneyintelX.dkd risk levels on repeat testing
and is significantly associated with improved outcomes*

LONDON and NEW YORK, 7 June 2025 - Renalytix plc (LSE: REXX) (OTCQB: RNLXY), a precision medicine company with *kidneyintelX.dkd*, the only FDA-approved and Medicare reimbursed prognostic test to support early-stage risk assessment in chronic kidney disease, announces that new pivotal data demonstrating how *kidneyintelX.dkd* enhances risk assessment over standard clinical measures alone thereby enabling more efficient treatment allocation, was presented at the prestigious European Renal Association Congress 2025 held in Vienna on 4-7 June.

The presentation titled "**Evaluating KDIGO and KidneyintelX.dkd for Risk Stratification in Diabetic Kidney Disease: Insights from CANVAS and CREDENCE**" was selected as one of the highest scoring abstracts for presentation.

The analysis included 2,954 subjects from the CANVAS and CREDENCE clinical trials who met the *kidneyintelX.dkd* intended use criteria and were randomized to treatment with SGLT2i or Placebo and followed for up to five years. The *kidneyintelX.dkd* risk level was assessed at baseline and at the one-year timepoint post randomization. Some of the key findings reported include:

- The *kidneyintelX.dkd* test reclassified 40% of patients to a different risk from baseline KDIGO risk levels category (e.g. from moderate to high/low, low to moderate, or high to moderate/low)
- Over the follow-up period, patients in the *kidneyintelX.dkd* high-risk level at baseline displayed a >20 times observed risk (after adjustment) compared to those classified as lowest risk by KDIGO
- Treatment with SGLT2i reduced the *kidneyintelX.dkd* levels significantly after one year compared to those not treated, with almost a 20% between group difference in the changes observed
- Patients who remained at high risk after one year had >4 times higher risk of events than those who were re-classified to moderate risk

Commenting on the newly presented data, Fergus Fleming, Chief Technology Officer, said: "*The kidneyintelX.dkd data highlights the importance of implementation of risk assessment and adoption of novel therapies such as SGLT2 inhibitors in early-stage chronic kidney disease as reflected in the 2024 KDIGO guidelines. The data shows that by targeting care to patients at highest risk of progression, a significant reduction in risk can be achieved in the short-term leading to improved outcomes for patients in the long-term. We believe there is strong clinical support to accelerate the implementation of guideline directed care to prevent unnecessary patient suffering and healthcare cost, and kidneyintelX.dkd is ideally placed to enable this.*"

The data analysis and presentation were co-authored by Renalytix and the University Medical Center Groningen as part of the PRIME-CKD consortium (<https://www.prime-ckd.com/>). Additional insights from the analysis will be presented at the American Diabetes Association Scientific Sessions on 19-23 June highlighting how *kidneyintelX.dkd* should be considered for enriching clinical trials and assessing treatment response:

Abstract 420-P, Baseline Risk and Longitudinal Changes in kidneyintelX.dkd Scores and Their Association with Kidney Outcomes in the CANVAS and CREDENCE Trials, H.L. Heerspink et al

<https://eppro02.ativ.me/src/EventPilot/php/express/web/planner.php?id=ADA25>

The complete analysis is being prepared for peer-reviewed publication later this year.

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About Renalytix (www.renalytix.com)

Renalytix (LSE: REXX) (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.

Uncontrolled and uncontrolled kidney disease progression are of the highest burden to patients. Uncontrolled progression to the

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 European Renal Association (<https://www.era-online.org/>)

With more than 28,000 members, the ERA (European Renal Association) is one of the biggest nephrology associations worldwide and one of the most important and prestigious European medical associations. It supports basic and clinical research in the fields of clinical nephrology, dialysis, renal transplantation and related subjects, and it is dedicated to advancing kidney health through science, education, and networking.

Founded in 1963, ERA serves as a leading platform for scientific exchange, professional development, and advocacy in the field of nephrology across Europe and beyond. ERA organises annual congresses and supports fellowships, and CME courses. ERA publishes two official leading nephrology journals in Europe: *Nephrology Dialysis Transplantation* and *Clinical Kidney Journal* (open access).

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