



## Renalytix Clinical Advisory Board Formed to Support Broadening Use of KidneyintelX.dkd

August 3, 2023

### World leading, multi-disciplinary experts advise on adoption of FDA authorized KidneyintelX.dkd across 14 million US patients with diabetes and chronic kidney disease

LONDON and SALT LAKE CITY, Aug. 03, 2023 (GLOBE NEWSWIRE) -- [Renalytix plc](#) (LSE: RENX) (NASDAQ:RNLX) announces the launch of its Clinical Advisory Board, a world-leading, multi-disciplinary clinical group, to help advance the use of FDA authorized kidneyintelX.dkd™ in mitigating uncontrolled kidney disease progression and guiding early stage treatment strategies for the estimated 14 million Americans with diabetic kidney disease.<sup>1</sup>

Commenting on the board's formation, Dr. Ralph DeFronzo said, "Now is the time when we can change the entire conversation around kidney disease from the current focus on better management of dialysis and transplant to preventative medicine and preserving kidney health early on. The confluence of new diagnostic technology, such as kidneyintelX.dkd, and new effective drug therapies, including SGLT2 inhibitors, has swung the door wide open to prevent millions of people from experiencing the life changing effects of uncontrolled kidney disease. We must now act deliberately to make sure primary care doctors, nurse practitioners and physician assistants across the U.S., and around the world, have access to these clinical advances."

Diabetic kidney disease (DKD) is a complication in up to 40% of patients with type 2 diabetes<sup>2</sup> and in approximately 60% of patients aged 65 years and older<sup>3</sup>. In multiple published studies, KidneyIntelX *in vitro prognostic* technology has shown the ability to provide reliable and actionable information to guide care and enable primary care physicians to recognize and act on early-stage kidney risk when therapies are most effective, thereby improving kidney health.

The Clinical Advisory Board members include:

- Stephen Brunton, MD, FAAFP, CDCES; University of North Carolina, Executive Director of Primary Care Metabolic Group (PCMG) and Editor-in-Chief of Clinical Diabetes
- Matthew Jay Budoff, MD, FACC, FAHA; David Geffen School of Medicine at UCLA and Endowed Chair of Preventive Cardiology at Harbor-UCLA Medical Center
- Barry I. Freedman, MD, FACP; John Felts Distinguished Professor and Chief of the Nephrology Section at Wake Forest University School of Medicine
- Ralph A. DeFronzo, MD; Professor of Medicine and Chief of the Diabetes Division at the University of Texas Health Science Center and the Deputy Director of the Texas Diabetes Institute
- Holly J. Mattix-Kramer MD, MPH; Division of Nephrology and Hypertension at Loyola University Chicago, Associate Director of Research for the Medicine Service Line and Founding Director of the Hines VA Serwa Research Center on Aging
- Javier Morales MD, FACP, FACE; Vice President and Principal Clinical Trials Investigator at Advanced Internal Medicine Group
- Joseph A. Vassalotti MD; Chief Medical Officer of the National Kidney Foundation (NKF) and Clinical Professor of Medicine in the Division of Nephrology at Icahn School of Medicine at Mount Sinai
- Eugene E. Wright Jr., MD; Duke University Medical Center and Medical Director for Performance Improvement at the Charlotte Area Health Education Center

Renalytix is dedicated to promoting early action to enhance the quality of life for individuals impacted by diabetic kidney disease with its risk assessment test, kidneyintelX.dkd. KidneyintelX.dkd is the only FDA approved risk assessment test, developed from the KidneyIntelX technology platform which has achieved broad scale reimbursement, for identifying risk for rapid kidney disease progression, thus enabling clinicians to intervene early with guideline-recommended actions. Clinical actions are most effective for preserving kidney and cardiovascular health in DKD stages 1-3 before significant and irreversible kidney function loss has occurred.

Based on the sheer numbers of people in the United States with type 2 diabetes (37 million)<sup>1</sup> and chronic kidney disease, (37 million)<sup>4</sup> early-stage patients are typically under the management of primary care practices. Renalytix will engage with the Clinical Advisory Board to provide an urgent call to action for primary care clinicians to diagnose, risk assess and treat their patients with stage 1-3 CKD, specifically in type 2 diabetics. The board will also advise the Company on education and outreach activities to promote adoption of best practices in kidney disease management, appropriate coordination with specialists including nephrologists and endocrinologists, and guideline recommendations.

## About Chronic Kidney Disease

Kidney disease is now recognized as a public health epidemic affecting over 850 million people globally. The Centers for Disease Control and Prevention (CDC) estimates that 15% of US adults, more than 37 million people<sup>4</sup>, currently have chronic kidney disease (CKD). Diabetes is the leading cause of kidney failure, accounting for 44% of new cases. Further, the CDC reports that 9 out of 10 adults with CKD do not know they have it and one out of two people with very low kidney function who are not on dialysis do not know they have CKD.<sup>5</sup> Kidney disease is referred to as a “silent killer” because it often has no symptoms and can go undetected until a very advanced stage. Each year, kidney disease kills more people than breast and prostate cancer. Every day, 13 patients in the United States die while waiting for a kidney transplant.

## About Type 2 Diabetes

More than 37 million Americans have diabetes (about 1 in 10)<sup>1</sup>, and approximately 90-95% of them have type 2 diabetes. Type 2 diabetes most often develops in people over age 45, but more and more children, teens, and young adults are also developing the disease<sup>6</sup>. Type 2 diabetes symptoms often develop over several years and approximately 23% of adults with Type 2 Diabetes are undiagnosed<sup>7</sup>. Type 2 diabetes affects many major organs, including the heart, blood vessels, nerves, eyes and kidneys. Diabetic kidney disease develops in 30-50% of Type 2 diabetes patients<sup>4</sup>.

## About Renalytix

Renalytix (NASDAQ: RNLX) (LSE: RENX) is an in-vitro diagnostics and laboratory services company that is the global founder and leader in the new field of bioprognosis™ for kidney health. The leadership team, with a combined 200+ years of healthcare and in-vitro diagnostic experience, has designed its KidneyIntelX laboratory developed test to enable risk assessment for rapid progressive decline in kidney function in adult patients with T2D and early CKD (stages 1-3). We believe that by understanding how disease will progress, patients and providers can take action early to improve outcomes and reduce overall health system costs. For more information, visit [www.renalytix.com](http://www.renalytix.com).

## About KidneyIntelX™

KidneyIntelX™ is a laboratory developed test demonstrated to be a reliable, bioprognostic™ methodology that yields a simple-to-understand, custom risk score, enabling prediction of which adult patients with T2D and early CKD (stages 1-3) are at low, intermediate or high risk for rapidly progressive decline in kidney function. By combining information from KidneyIntelX with newer cardio- and reno-protective therapies, doctors will have more information in determining which patients are at higher versus lower risk for rapid disease progression and may be able to more appropriately target resources and guideline-recommended treatments to advance kidney health. KidneyIntelX is supported by a growing body of clinical, utility and health economic studies (including a validation study of two large cohorts) and has demonstrated a 72% improvement in predicting those patients who are at high risk for rapid progressive decline in kidney function versus the current standard of care (eGFR and UACR). To learn more about KidneyIntelX and review the evidence, visit [www.kidneyintelx.com](http://www.kidneyintelx.com).

## Sources

1. Centers for Disease Control and Prevention. <https://www.cdc.gov/diabetes/basics/index.html>
2. Gheith O, Farouk N, Nampoory N, et al. Diabetic kidney disease: worldwide difference of prevalence and risk factors. *J Nephropharmacol*. 2015 Oct 9;5(1):49-56. PMID: 28197499; PMCID: PMC5297507
3. Wu B, Bell K, Stanford A, et al. Understanding CKD among patients with T2DM: prevalence, temporal trends, and treatment patterns—NHANES 2007–2012. *BMJ*
4. <https://www.cdc.gov/kidneydisease/basics.html>
5. <https://www.theisn.org/blog/2020/11/27/more-than-850-million-worldwide-have-some-form-of-kidney-disease-help-raise-awareness/>
6. <https://www.cdc.gov/diabetes/basics/type2.html>
7. <https://www.cdc.gov/diabetes/data/statistics-report/index.html>

## Forward Looking Statements

Statements contained in this press release regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Examples of these forward-looking statements include statements concerning: the potential benefits, including economic savings, of KidneyIntelX, the impact KidneyIntelX can have on patients’ enhanced understanding of kidney disease and motivation to make lifestyle changes, the commercial prospects of KidneyIntelX, including whether and to what extent KidneyIntelX will be successfully adopted by physicians and distributed and marketed, our expectations regarding reimbursement decisions and the ability of KidneyIntelX to curtail costs of chronic and end-stage kidney disease, optimize care delivery, address systemic inequalities and improve patient outcomes. Words such as “anticipates,” “believes,” “estimates,” “expects,” “intends,” “plans,” “seeks,” and similar expressions are intended to identify forward-looking statements. We may not actually achieve the plans and objectives disclosed in the forward-looking statements, and you should not place undue reliance on our forward-looking statements. Any forward-looking statements are based on management’s current views and assumptions and involve risks and uncertainties that could cause actual results, performance, or events to differ materially from those expressed or implied in such statements. These risks and uncertainties include, among others: that KidneyIntelX is based on novel artificial intelligence technologies that are rapidly evolving and potential acceptance, utility and clinical practice remains uncertain; we have only recently commercially launched KidneyIntelX; and risks relating to the impact on our business of the COVID-19 pandemic or similar public health crises. These and other risks are described more fully in our filings with the Securities and Exchange Commission (SEC), including the “Risk Factors” section of our annual report on Form 20-F filed with the SEC on October 31, 2022, and other filings we make with the SEC from time to time. All information in this press release is as of the date of the release, and we undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

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