FDA Grants De Novo Marketing Authorization for KidneyIntelX.dkd to Assess Risk of Progressive Kidney Function Decline in Adults with Diabetes and Early-Stage Kidney Disease

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Simple Blood Test Aids Risk Assessment for Approximately 14 Million Eligible Patients in the United States

Diabetic Kidney Disease is the Leading Cause of End Stage Kidney Disease in the United States

LONDON and SALT LAKE CITY, June 29, 2023 (GLOBE NEWSWIRE) -- Renalytix plc (LSE: RENX) (NASDAQ:RNLX) announces that the U.S. Food and Drug Administration (FDA) has granted De Novo marketing authorization for its KidneyIntelX.dkd ™ prognostic test. This affirms KidneyIntelX as a first-in-class, artificial intelligence enabled prognostic testing platform to guide care management for adults with type 2 diabetes and early-stage chronic (diabetic) kidney disease. Renalytix believes FDA authorization will lead to increasing test adoption, informing clinical guidelines, expanding insurance coverage, and pursuing additional international regulatory approvals.

“Meeting the rigorous safety, clinical and analytical validation, and scientific data requirements of an FDA review, from Breakthrough Device designation to De Novo marketing authorization, is a landmark event for health care providers and patients with diabetic kidney disease,” said James McCullough, CEO of Renalytix. “With this approval a new class, Prognostic Test for Assessment of Chronic Kidney Disease Progression, has been established by the FDA, providing a roadmap for future expansion of KidneyIntelX into new indications and products.”

KidneyIntelX.dkd accurately stratifies patients into three risk levels (low, moderate, and high). This result provides comprehensive information on patient risk for progressive decline in kidney function within five years, independently of the current standard of care measures. KidneyIntelX.dkd is the name used to differentiate tests to be provided under the De Novo marketing authorization by the FDA from those provided under the KidneyIntelX name as a Laboratory Developed Test.

Since being introduced as a Laboratory Developed Test (LDT), KidneyIntelX results have been reported on approximately 10,000 patients in the United States and there has been broad insurance payment including from Medicare and many private payers.

The KidneyIntelX platform combines blood-based biomarkers with clinical variables using an artificial intelligence enabled algorithm, providing reliable and actionable information to guide care in large, at-risk patient populations. KidneyIntelX is based on technology developed at the Icahn School of Medicine at Mount Sinai in New York, NY, and licensed to Renalytix.

About Chronic (Diabetic) 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 38 million people, 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.[1] 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), 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[2]. Type 2 diabetes symptoms often develop over several years and approximately 23% of adults with Type 2 Diabetes are undiagnosed[3]. 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[4].

Sources

1 https://www.theisn.org/blog/2020/11/27/more-than-850-million-worldwide-have-some-form-of-kidney-disease-help-raise-awareness/
2 https://www.cdc.gov/diabetes/basics/type2.html
3 https://www.cdc.gov/diabetes/data/statistics-report/index.html
4 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5297507/

About Renalytix

Renalytix (NASDAQ: RNLX) (LSE: RENX) 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 technology platform to introduce novel laboratory developed and FDA approved tests to enable risk assessment and appropriate care management in adult patients with type 2 diabetes and early-stage CKD. By gaining early visibility into risk for progressive decline in kidney function, and an understanding of associated actionable insights, patients and health care providers may benefit from improved outcomes and decreased costs. For more information, visit our Company website at www.renalytix.com and our product website at www.kidneyintelx.com.

KidneyIntelX is based on technology developed at the Icahn School of Medicine at Mount Sinai in New York, NY, and licensed to Renalytix. Mount Sinai and Mount Sinai faculty have a financial interest in Renalytix. Mount Sinai also has representation on the Renalytix Board of Directors.

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 commercial prospects of KidneyIntelX and KidneyIntelX.dkd, including whether KidneyIntelX and KidneyIntelX.dkd will be successfully adopted by physicians, inform clinical guidelines, achieve expanded insurance coverage and be successfully distributed and marketed, the potential for KidneyIntelX and KidneyIntelX.dkd to be expanded and approved for additional indications and in additional jurisdictions, our expectations regarding reimbursement decisions and the ability of KidneyIntelX and KidneyIntelX.dkd to curtail costs of chronic and end-stage kidney disease, optimize care delivery 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 and KidneyIntelX.dkd are 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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