US Patent Office Allows Patent Claims for IP

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

US Patent Office Allows Patent Claims for Intellectual Property Exclusively Licensed to Renalytix

LONDON and SALT LAKE CITY - October 6, 2023 - Renalytix plc (NASDAQ: RNLX) (LSE: RENX), the first company to commercialize an FDA authorized artificial intelligence (AI) enabled blood test to assess risk of progressive kidney function decline for individuals with type 2 diabetes and early-stage chronic kidney disease, announces that the US Patent Office has issued a new notice of allowance of claims surrounding the biomarkers sTNFR1 and sTNFR2 used in the kidneyintelX.dkd test. These claims were filed under US Patent Application No. 16/671.256 by the Joslin Diabetes Center and this patent is exclusively licensed to Renalytix. KidneyintelX.dkd received Food and Drug Administration de Novo marketing authorization on June 29, 2023.

The newly allowed claims further strengthen the core intellectual property underpinning the KidneyIntelX technology by directly incorporating sTNFR1 and sTNFR2 into a set of consolidated claims directed towards identifying risk of early kidney function decline, thereby enabling therapeutic strategies for those at increased risk of progressive decline.

The Company believes this development reflects the Renalytix strategy of innovation in biomarker research, development and translation in collaboration with the Joslin Diabetes Center and other leading research partners globally. When taken together with other key milestones, such as FDA De Novo marketing authorization, broad insurance coverage and published clinical utility and outcomes data, Renalytix believes this increases its competitive advantage. The Company also believes this creates further barriers to entry in the large addressable market for optimizing clinical management of kidney disease to drive improved patient outcomes. A similar strategy to protect Renalytix's intellectual property is being pursued in Europe, which also presents a large opportunity for KidneyIntelX expansion.

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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 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].

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.

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/

Forward Looking Statements

Statements contained in this announcement 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 the impact and benefits of the CMS action on the value or pricing of KidneyIntelX, our expectations reimbursement decisions, our intellectual property position, our competitive position 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. Inclusion of KidneyIntelX in the draft KDIGO guidelines does not guarantee inclusion in the final guidelines. 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 10-K filed with the SEC on September 28, 2023, 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.