



RenalytixAI to Collaborate with AstraZeneca

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Renalytix AI plc
("RenalytixAI", the "Company")

RenalytixAI to Collaborate with AstraZeneca to Improve Outcomes for Patients with Chronic Disease

*Parties to adopt multi-phase approach to develop precision medicine strategies to
optimize treatment of cardiovascular, renal and metabolic disease*

NEW YORK, August 21, 2020 - [Renalytix AI plc](#) (LSE: RENX) (NASDAQ: RNLX), today announced a collaboration with AstraZeneca (LSE/STO/NYSE: AZN) to develop and launch precision medicine strategies for cardiovascular, renal and metabolic diseases. The first stage in the collaboration will use KidneyIntelX, an artificial intelligence-enabled *in vitro* diagnostic platform, to examine further improving outcomes for patients with chronic kidney disease (CKD) and its complications, in coordination with the Mount Sinai Health System. The goal of the first stage is to help improve guideline-based standard-of-care for optimal utilization of existing and novel therapeutics using the KidneyIntelX testing platform and proprietary care management software.

An estimated 700 million patients worldwide have CKD,¹ which is also associated with an increased risk of metabolic and hematologic complications, such as hyperkalemia (elevated levels of potassium in the blood) and anemia.^{2,3}

The first stage will assess the impact of AI-enabled *in vitro* diagnostic solutions to optimize utilization of therapeutics in CKD under current standard of care protocols. Based on study outcomes, a multi-center, randomized controlled trial will be initiated to evaluate uptake and adherence to new potassium-binding agents in patients with CKD and hyperkalemia. The studies will be conducted in coordination with the Mount Sinai Health System, where KidneyIntelX testing and care management software are currently being deployed for commercial clinical use.

"We believe this collaboration will define how we can leverage KidneyIntelX to improve the care and outcomes for patients affected by chronic diseases, such as kidney disease, diabetes, and cardiovascular disease," said Barbara Murphy, MD, Chair of the Samuel Bronfman Department of Medicine, Dean for Clinical Integration and Population Health Management at the Icahn School of Medicine at Mount Sinai, and board

member of RenalytixAI. *"By using a more personalized approach, our initial goal is to help realize improved outcomes for more than 240,000 patients with chronic kidney disease within the Mount Sinai Health System."*

RenalytixAI and AstraZeneca will use KidneyIntelX with the aim to:

- Help improve physician uptake and patient adherence to existing potassium-binding therapeutics and other approved products in CKD through early identification of previously hidden high-risk patient groups
- Accelerate patient identification and recruitment for clinical trials
- Complement commercialization efforts with outcomes from KidneyIntelX results

"This collaborative approach reflects the shared vision of AstraZeneca and RenalytixAI to develop meaningful solutions to tackle significant challenges in healthcare in a holistic way," said Tarek Rabah, Vice President, AstraZeneca US Renal-Cardio. "We are committed to revolutionizing kidney care by continuing to drive innovation. An important component of our work is identifying patients with significant unmet need and providing them with more personalized interventions."

Results from the program are anticipated in early 2021.

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About Chronic Kidney Disease

CKD is a serious, progressive condition defined by decreased kidney function (shown by reduced eGFR or markers of kidney damage, or both, for at least three months).⁵ In the United States alone, nearly 37 million American adults (15%) currently have CKD.⁶ Meanwhile, on a global scale, the total number of individuals with CKD, acute kidney injury (AKI), and those on renal replacement therapy (RRT) exceeds 850 million.⁷

The disease often has no symptoms in its early stages and can go undetected until it is very advanced requiring dialysis or a kidney transplant. The Centers for Disease Control and Prevention (CDC) reports that 9 out of 10 adults with CKD go undiagnosed, and half of

patients with very low kidney function, who are not on dialysis, do not know they have CKD.⁶For this reason, kidney disease is often referred to as a "silent disease."⁸

As kidney function declines, patients face an increased risk of developing other associated CKD complications, such as anemia or hyperkalemia.^{2,3} Anemia is a serious medical condition in which patients have insufficient red blood cells and low levels of hemoglobin ("Hb"), a protein in red blood cells that carries oxygen to cells throughout the body.³ If left untreated, anemia of CKD can cause increased hospitalization, morbidity and mortality.⁹ Hyperkalemia can also be a dangerous condition, characterized by elevated potassium levels in the blood.² If left untreated, it can cause an irregular heartbeat and can be fatal.

About RenalytixAI

We are a commercial-stage artificial intelligence-enabled *in vitro* diagnostics company, focused on optimizing clinical management in chronic kidney disease to help drive improved patient outcomes and significantly lower healthcare costs. KidneyIntelX, our first-in-class diagnostic platform, employs a proprietary artificial intelligence-enabled algorithm that combines diverse data inputs, including validated blood-based biomarkers, inherited genetics and extensive personalized patient data from electronic health record systems to generate a unique patient risk score. KidneyIntelX is based on technology developed by Mount Sinai faculty and licensed to RenalytixAI. Mount Sinai and Mount Sinai faculty, including a small number of inventors and Barbara Murphy, MD, have a financial interest in RenalytixAI.

About the Mount Sinai Health System

The Mount Sinai Health System is New York City's largest academic medical system, encompassing eight hospitals, a leading medical school and a vast network of ambulatory practices throughout the greater New York region. Mount Sinai is a national and international source of unrivaled education, translational research and discovery and collaborative clinical leadership ensuring that we deliver the highest quality care-from prevention to treatment of the most serious and complex human diseases. The Health System includes more than 7,200 physicians and features a robust and continually expanding network of multispecialty services, including more than 400 ambulatory practice locations throughout the five boroughs of New York City, Westchester and Long Island. The Mount Sinai Hospital is ranked No. 14 on *U.S. News & World Report's* "Honor Roll" of the Top 20 Best Hospitals in the country and the Icahn School of Medicine as one of the Top 20 Best Medical Schools in country. Mount Sinai Health System hospitals are consistently ranked regionally by specialty and our physicians are in the top 1% of all physicians nationally by *U.S. News & World Report*.

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: our ability to improve outcomes for patients with chronic disease and develop precision medicine strategies to optimize treatment of cardiovascular, renal and metabolic disease, as well as the anticipated benefits of the collaboration with AstraZeneca, including optimizing utilization of existing and novel therapeutics, accelerating patient identification and recruitment for clinical trials and complementing commercialization efforts. 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 not yet 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 final prospectus filed with the Securities and Exchange Commission (SEC) on July 17, 2020, 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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References:

1. Global, regional, and national incidence, prevalence, and years lived with disability for 354 diseases and injuries for 195 countries and territories, 1990-2017: asystematic analysis for the Global Burden of Disease Study 2017. The Lancet. 2018; 392:1789-858. [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(18\)32279-7/fulltext#seccestitle10](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)32279-7/fulltext#seccestitle10). Published November 10, 2018. Accessed August 4, 2020.
2. National Kidney Foundation. Clinical Update on Hyperkalemia. 2016. <https://www.kidney.org/sites/default/files/02-10-7260%20Clinical%20Bulletin.pdf>
3. National Institute of Diabetes and Digestive and Kidney Disease. Anemia in Chronic Kidney Disease. <https://www.niddk.nih.gov/health-information/kidney-disease/anemia#:~:text=What%20causes%20anemia%20in%20chronic,of%20the%20oxygen%20it%20needs>. Published November 8, 2014. Accessed August 4, 2020.
4. Desai NR, Reed P, Alvarez PJ, et al. The Economic Implications of Hyperkalemia in a Medicaid Managed Care Population. American Health & Drug Benefits. 2019.12(7)352-361. <http://www.ahdbonline.com/issues/2019/november-2019-vol-12-no-7/2862-the-economic-implications-of-hyperkalemia-in-a-medicare-managed-care-population>. Accessed August 4, 2020.
5. Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group. KDIGO 2012 clinical practice guideline for the evaluation and management of chronic kidney disease. Kidney International Supplement 2013; (3):1-150. Accessed August 4, 2020.

6. Centers for Disease Control and Prevention. Chronic Kidney Disease in the United States, 2019. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2019. Accessed August 4, 2020.
7. A Hidden Epidemic: More than 850 Million Suffer from Kidney Diseases Worldwide, Organizations Report. ASN Kidney News. https://www.kidneynews.org/kidneynews/10_8/4/4.pdf. Published August 2018. Accessed August 4, 2020.
8. National Institute of Diabetes and Digestive and Kidney Disease. Kidney Disease Statistics for the United States. <https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease>. Updated 2020. Accessed August 4, 2020.
9. Thorp M, Johnson S, Yang X, et al. Effect of anaemia on mortality, cardiovascular hospitalizations and end-stage renal disease among patients with chronic kidney disease. *APSN*. 2009;14(2):240-246. doi:10.1111/j.1440-1797.2008.01065.x.

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