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NEWS RELEASE

New Study Highlights Novel CBD Sublingual Wafer's Potential in Improving Quality of Life for People with Kidney Failure

- SEISMIC-CBD study suggests safety and tolerability of the novel freeze-dried cannabidiol (CBD) sublingual wafer, formulated with iX Biopharma's patented WaferiX delivery technology ("**CBD wafer**"), in patients with kidney failure.

- Improvements were observed in symptoms such as sleep quality, restless legs syndrome (RLS), anorexia, pain, and anxiety.

Sydney, Australia, 12 August 2024 — iX Biopharma Ltd. (the "**Company**"), a specialty pharmaceutical company specialising in drug delivery systems and a leader in innovative healthspan nutraceuticals, has announced results from the SEISMIC-CBD study led by Dr Brendan Smyth from the NHMRC Clinical Trials Centre and sponsored by the University of Sydney (SESLHD 2021/ETH11655). This investigator-initiated research evaluated the safety and tolerability of the Company's CBD wafers in patients with kidney failure, including those receiving dialysis therapy. This study marks a significant milestone as the first to investigate CBD's effects in this patient population that experiences high rates of multiple medical conditions.

Kidney failure is a severe disease affecting over 12 million people globally. It brings a heavy burden of symptoms such as pain, nausea, anorexia, pruritus, insomnia, restless legs syndrome (RLS), and tiredness. Drugs need to be carefully studied in this patient population because impaired kidney function can significantly alter the pharmacokinetics and pharmacodynamics of medications, potentially leading to reduced efficacy or increased rates of adverse effects.

Study Design and Results

The SEISMIC-CBD study was a single-arm prospective trial involving 12 patients with kidney failure (eGFR less than or equal to 15ml/min/1.73m^2 or receiving maintenance dialysis). Patients received the CBD wafers in a supervised dose escalation over two weeks followed by a further four weeks of treatment.

Key findings from the study include:

- The CBD wafer was safe and generally well-tolerated, with no serious adverse events reported.
- Among the seven patients who completed the full six-week treatment period, three reported that symptoms were 'very much' improved, two reported symptoms were 'much improved,' one each reported 'minimally improved' and 'no change', respectively. Four patients chose to continue using the CBD wafers post-study.
- Overall, statistically significant improvements were noted in multiple symptom domains measured with the Edmonton Symptom Assessment Scale-Renal (ESAS-R), including sleep quality, RLS, anxiety, anorexia, and pain.
- Adverse events reported as possibly related to the CBD wafers included nausea, dizziness and drowsiness. Four patients did not complete the full six-week treatment

period due to mild adverse events (two patients) and lack of symptom improvement (two patients). One patient passed away from kidney disease.

The findings of this small study provide important data indicating that CBD, which is predominantly metabolised in the liver, may not be significantly affected by severely reduced kidney function and supports the conduct of larger, controlled studies.

The full study results will be presented at the upcoming 59th ANZSN (Australian and New Zealand Society of Nephrologists) Scientific meeting held in Adelaide in September 2024.

Dr. Brendan Smyth, Principal Investigator, The University of Sydney, stated, *"The SEISMIC-CBD study is an important step towards proving that CBD can be safely used in patients with kidney failure. As the first published study of CBD in kidney failure patients, SEISMIC-CBD lays the groundwork for further research to fully explore CBD's therapeutic potential in this patient group.*"

Dr. Janakan Krishnarajah, Chief Operating Officer and Chief Medical Officer of iX Biopharma, added, *"The success of iX Biopharma's novel CBD sublingual wafers in this study underscores our commitment to developing innovative products for unmet medical needs. We are excited about the results of the study, which advances our knowledge of CBD."*

The CBD wafer is an unapproved medicine and only available in Australia under the Special Access Scheme and Authorised Prescribers pathways for unapproved medicines.

About iX Biopharma Ltd

iX Biopharma is a specialty pharmaceutical and nutraceutical company listed on the Catalist board of the Singapore Exchange Securities Trading Limited (SGX-ST), operating a fully integrated business model from drug development to manufacturing and supply, with facilities in Australia. The Group is focused on the development and commercialisation of pharmaceutical drugs and innovative nutraceuticals using novel, patent-protected formulations for sublingual delivery.

iX Biopharma has developed a number of patented drug delivery platform technologies, including WaferiX, WaferlogiX and NADiX, which deliver small molecule and biologics sublingually via the mucosa for better absorption, faster onset of action and predictable effect. The drug delivery platforms are particularly useful for drug repurposing, where existing approved drugs are developed into new drugs targeting different indications or a different route of administration, at a lower development cost and risk. iX Biopharma's portfolio includes among others, ketamine, dexmedetomidine, medicinal cannabis and healthspan products.

About the University of Sydney

As Australia's first university – founded in 1850 – the University of Sydney has a proud history of global leadership in education and research and inspiring people from all backgrounds to contribute to positive real-world change. The University of Sydney is a world-renowned teaching and research institution – our research combines the expertise and talents of scholars from many disciplines. For further details, please visit its website at https://www.sydney.edu.au/about-us.html.

About the NHMRC Clinical Trials Centre, University of Sydney

The NHMRC Clinical Trials Centre is a flagship research centre of the Faculty of Medicine and Health at the University of Sydney that designs and manages clinical trials. This includes responsibility for study coordination, monitoring, data acquisition and management and statistical analysis. The NHMRC Clinical Trials Centre has health economics, biostatistics, systematic reviews and biomarker teams work with trial data and inform healthcare providers about best practice. For further details, please visit its website at https://www.ctc.usyd.edu.au/.

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