
NEWS RELEASE**IX BIOPHARMA SUCCESSFULLY COMPLETES PHASE 1
SUBLINGUAL DEXMEDETOMIDINE CLINICAL STUDY**

Clinical study yielded excellent results:

- ✓ Achieved high absolute bioavailability of 70-80%
- ✓ Fast onset of action with early detectable plasma drug levels
- ✓ Demonstrated safety and tolerability

Singapore, 10 February 2023 – iX Biopharma Ltd (the “**Company**”) (SGX:42C) is pleased to announce the successful completion of a Phase 1 pharmacokinetic clinical study on the sublingual dexmedetomidine wafer being developed by the Company. The drug is being developed for the treatment of dementia-related agitation, which is an unmet medical need with no drug treatment approved to-date.

The clinical study is a 4-way crossover study to evaluate the safety, tolerability and pharmacokinetics of the sublingual dexmedetomidine wafers in 14 healthy volunteers. The study assessed the absolute bioavailability of sublingual dexmedetomidine wafers across the respective dosages of 30mcg, 50mcg, and 100mcg when compared to the intravenous administration of dexmedetomidine, Precedex® at 20mcg.

The Phase 1 pharmacokinetic clinical study achieved several promising results:

1. **High bioavailability:** The sublingual wafer showed an impressive 70-80% absolute bioavailability across all dosages tested.
2. **Fast onset of action:** The sublingual wafer achieved a peak drug concentration in 1.5 hours (T_{max}), with drug detectable in plasma as early as 5 minutes post dosing.
3. **Dose proportional:** The drug exposure was proportional across the dosing range.
4. **Safety profile:** Sublingual wafers were safe and well tolerated; there were no serious adverse events.

“These promising results validates the potential of our sublingual dexmedetomidine wafers in revolutionising the treatment of agitation in dementia patients and gives us confidence to advance this development programme,” said **Eddy Lee, iX Biopharma’s Chairman and CEO**. *“With an aging global population, the prevalence of dementia continues to rise, leading to an estimated 100 million episodes of agitation per year in the USA alone. Our sublingual wafers have the potential to greatly improve patient outcomes and make a significant impact in their care.”*

Following the success of Phase 1, the Company plans to file an Investigational New Drug application with US Food and Drug Administration to conduct a Phase 2 study on patients with dementia-related agitation.

The Company announced the launch of its sublingual dexmedetomidine development programme in August 2022. The product is formulated with the Company's patented WaferiX technology and has the potential to be used for the treatment of multiple indications including dementia-related agitation. This is part of iX Biopharma's plan to expand its pipeline and further its strategy to repurpose existing approved drugs using its proprietary WaferiX drug delivery platform to target new therapeutic areas with unmet or significant medical need.

Dementia is one of the leading causes of disability for elderly adults¹ globally, and spending on managing the condition exceeds USD 1 trillion annually. In 2020, more than 5.8 million people in the United States were living with Alzheimer's disease (the most common type of dementia²), and these persons collectively experience an aggregate of over 100 million agitation episodes annually³. There are currently no FDA-approved therapies for the treatment of this condition.

iX Biopharma's sublingual dexmedetomidine wafer is administered by placing the wafer under the tongue, for rapid disintegration, greater absorption and improved bioavailability. Patients may benefit from faster and more predictable therapeutic action. Moreover, the drug is non-invasive, non-traumatic, convenient and easy to use during out-patient care.

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 therapies for diseases of the central nervous system using novel, patent-protected formulations for sublingual delivery.

iX Biopharma has developed a patented drug delivery platform technology, WaferiX. WaferiX delivers drug sublingually via the mucosa for better absorption, faster onset of action and predictable effect. The WaferiX delivery platform is particularly useful for drug repurposing which is a growing trend with a global market worth over US\$30 billion⁴. Drug repurposing is 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. Other than Wafermine, iX Biopharma's portfolio includes among others, medicinal cannabis, sildenafil and buprenorphine sublingual wafers.

¹ <https://www.oecd.org/fr/sante/care-needed-9789264085107-en.htm>

² <https://www.cdc.gov/aging/dementia/index.html>

³ <https://www.transparencymarketresearch.com/acute-agitation-and-aggression-treatment-market.html>

⁴ <https://www.intechopen.com/books/drug-repurposing-hypothesis-molecular-aspects-and-therapeutic-applications/drug-repurposing-dr-an-emerging-approach-in-drug-discovery>



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