Kinoxis secures $14.5m in funding and announces expansion of clinical programs to target agitation and aggression in dementia patients

- $14.5m Series B funding raised, with support from key investors Uniseed, UniSuper, University of Sydney, Stoic VC, Avicella Capital, as well as sophisticated investors.
- Funding will underpin the company's Phase 2 clinical programs for lead asset, KNX100.
- KNX100 is being developed for the treatment of behavioural and psychological symptoms in various neuropsychiatric disorders, including dementia and substance use disorders.
- New Phase 2 study focused on treatment of agitation and aggression in patients with dementia follows highly compelling preclinical data showing KNX100 is competitive with leading therapeutic used for symptom management
- The first Australian study of its kind will commence this month.

MELBOURNE, AUSTRALIA, 12th August 2024 - Kinoxis Therapeutics, an Australian clinical stage biotechnology company developing novel therapies for behavioural and psychological symptoms in neuropsychiatric disorders, is pleased to announce that it has secured $14.5m in new funding through a Series B financing round. The raise was heavily supported by key existing investors at Uniseed, Australia's longest-running venture fund, UniSuper, one of Australia's largest superannuation funds, the University of Sydney, Stoic VC, and new US based investor Avicella Capital. The round was also well support by existing and new sophisticated investors.

The funds raised will be used to support Phase 2 programs for Kinoxis' lead drug candidate, KNX100. Being developed as a transdiagnostic treatment, KNX100 addresses behavioural and psychological symptoms across multiple indications, including agitation and aggression in dementia and several substance use disorders.

In August, Kinoxis will commence a Phase 2 study examining the safety, tolerability and efficacy of KNX100 when used as a treatment of agitation in dementia patients. First of its kind in Australia, this study, named CARES-X, will be conducted across 8 sites with 60 patients[1].

The Australian Institute of Health and Welfare estimated that in 2023 there were 411,100 Australians living with dementia. This number has been predicted to more than double by 2058, to 849,300. Agitation and aggression are common symptoms in late-stage dementia patients, affecting around 76% of individuals with the condition[2].

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[1] ACTRN 12624000747527

[2] Source: https://pubmed.ncbi.nlm.nih.gov/24962058/

Hugh Alsop, CEO of Kinoxis Therapeutics, said: “This injection of funding comes at an important time. We are targeting a significant unmet treatment need for dementia patients, potentially broadening the options for them to maintain a higher quality of life. This is a new and highly promising area of development for KNX100, and we are grateful to have had the strong support from our major investors, who are keen to see us take KNX100 into human trials, following our highly encouraging preclinical results.”

Agitation and aggression in dementia have a profound impact on caregivers, who on average provide five hours of supervision per day to the patients under their care[3]. Unfortunately, these behavioural and psychological symptoms often drive the transition to assisted living facilities, resulting in a significant economic burden[4] to the public healthcare system.

In preclinical studies, KNX100 reduced aggression and agitation-like behaviour across multiple preclinical models, including a genetic model of Alzheimer’s disease, which is the most common form of dementia. KNX100 normalises activity in brain circuits that are key regulators of negative emotional states and aggression. KNX100 also showed superior results compared to Risperidone, an atypical antipsychotic which is commonly used off-label for managing these symptoms.

A Phase 1 first-in-human clinical trial for KNX100 was completed in December, 2023. This study achieved its primary endpoints, demonstrating safety and tolerability in healthy volunteers.

“Preclinical studies and excellent safety outcomes in the Phase 1 study led us to the Phase 2 program to specifically explore KNX100’s safety and efficacy in treating agitation and aggression in dementia patients. Notably, KNX100 reduced agitation and aggression symptoms in animal models, without the major sedative and cardiovascular safety liabilities of atypical antipsychotics such as arrhythmia, hypertension and sudden cardiac death[5]. We see this as a promising sign that KNX100 has the potential to make a real difference to the lives of dementia patients and their caregivers,” said Mr Alsop.

Currently, there is only one FDA (but no TGA) approved drug on the market that targets agitation associated with dementia due to Alzheimer’s disease. This treatment, which carries an FDA-issued black box warning, may increase the risk of death in elderly

[3] Source: https://www.who.int/news-room/fact-sheets/detail/dementia
[4] Source: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6881649/
[5] Source: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/205422s009lbl.pdf

patients with dementia-related psychosis. The current agitation and aggression market size is estimated to be US$5.2 billion.

Peter Devine, Chairman of Kinoxis Therapeutics and CEO of Uniseed said: “As long-term investors, we are excited to see Kinoxis investigate new areas of therapeutic applications using one of the company’s key assets. It is also encouraging to see Australia continue to be a breeding ground for world-class clinical development. We look forward to seeing the result of the Phase 2 trial and the impact it brings to dementia patients and carers.”

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About Kinoxis Therapeutics:

Kinoxis Therapeutics Pty Ltd (Kinoxis) is a private, Australian-based, clinical-stage biotechnology company developing first-in-class therapeutics to address the escalating demand for safe and effective treatments for behavioural and psychological symptoms in neuropsychiatric disorders.

Kinoxis' lead candidate, KNX100, is being developed for the treatment of behavioural and psychological symptoms in neuropsychiatric disorders, including agitation and aggression in dementia, and several substance use disorders. KNX100 has a novel mechanism of action, interacting with disease relevant pharmacological, molecular, and neural targets, to modify the dysregulated brain systems linked with specific behavioural and psychological symptoms in neuropsychiatric disorders. The compound has an extensive pre-clinical data package consisting of multiple cross-species animal efficacy models conducted across several independent research organisations. Kinoxis have completed a Phase 1 study conducted under a US IND and have demonstrated KNX100 to be safe and tolerable in healthy volunteers. Kinoxis has also secured significant funding from the US NIH/NIDA for the development of KNX100 as a treatment for opioid use disorder through grants 1UG3DA048743-01 and 4UH3DA048743-02.

In addition, to the KNX100 program, Kinoxis have a strategic partnership and licensing agreement with Boehringer Ingelheim to develop first-in-class oxytocin receptor targeting precision psychiatry treatments to improve the quality of life of people living with neuropsychiatric disorders.

Learn more at www.kinoxistherapeutics.com.