



MEDIA RELEASE

Kinosis Announces Plan to Evaluate KNX100 for the Treatment of Alcohol Use Disorder

- *KNX100 is a novel small molecule being developed as a transdiagnostic treatment for substance use disorders, including alcohol use disorder.*
- *A recently completed Phase 1 clinical trial demonstrated the safety and tolerability of KNX100 in healthy volunteers.*
- *An additional Phase 1 clinical trial will evaluate the pharmacodynamic and pharmacokinetic interaction of KNX100 and alcohol.*

MELBOURNE, AUSTRALIA, 13 May 2024

Kinosis Therapeutics announced today a collaboration with the U.S. National Institute on Alcohol Abuse and Alcoholism (NIAAA) to evaluate Kinosis' lead compound, KNX100, in alcohol use disorder, under an executed Clinical Trial Agreement (CTA). The CTA is just the first step in the Kinosis and NIAAA collaboration towards developing a safe and effective treatment for alcohol use disorder. Plans for NIAAA to conduct a Phase 1 clinical trial to evaluate the pharmacodynamic and pharmacokinetic interaction of KNX100 under the agreement still await Institutional Review Board (IRB) approval as well as Investigational New Drug Application (IND) approval by the U.S. Food and Drug Administration (FDA).

Alcohol misuse is one of the leading causes of preventable death, claiming over 3 million lives each year¹. It is estimated that over 250 million individuals met the criteria for alcohol use disorder globally². Despite this, only 2.1% of people with alcohol use disorder in the US received medication-assisted treatment, highlighting a significant treatment gap³. Treating alcohol use disorder requires a comprehensive approach that combines psychosocial interventions and pharmacotherapy to address the dysregulated brain systems associated with the disorder, ultimately aiming to reduce craving, compulsive use, and impaired control.

The collaboration between Kinosis and the NIAAA marks a hopeful step in the development of KNX100 for alcohol use disorder. "We are extremely excited to work with the NIAAA, who have deep expertise and experience in alcohol use disorder," said Hugh Alsop, CEO of Kinosis.

About KNX100

Kinosis' lead candidate, KNX100, is being developed as a transdiagnostic treatment for substance use disorders. In a Phase 1 study conducted under a US IND, KNX100 was demonstrated to be safe and tolerable in healthy volunteers. The compound has an extensive pre-clinical data package consisting of multiple efficacy models across alcohol, opioid, cocaine, methamphetamine, and nicotine use disorders in various species, validated across multiple institutions. KNX100 has a novel mechanism of action, interacting with disease relevant pharmacological, molecular, and neural targets, to modify the dysregulated brain systems linked with substance use disorders. Kinosis plans on initiating several clinical studies across alcohol, opioid, and stimulant use disorders, with the alcohol use disorder program being conducted in partnership with the NIAAA under a CTA.



About Kinosis Therapeutics

Kinosis Therapeutics is a private, Australian-based, clinical stage biotechnology company developing first-in-class therapeutics to address the escalating demand for effective treatments for substance use disorders and social dysfunction in neurological and psychiatric disorders. Kinosis' development candidates are novel, small molecules that were discovered through a comprehensive medicinal chemistry and screening program at the University of Sydney, Australia. Kinosis is backed by Uniseed, Australia's longest running venture fund, and a consortium of sophisticated investors. Kinosis 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, Kinosis has an existing strategic partnership and licensing agreement with Boehringer Ingelheim for the development of 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

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References:

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2. WHO: <https://www.who.int/news/item/21-09-2018-harmful-use-of-alcohol-kills-more-than-3-million-people-each-year--most-of-them-men>
3. NIAAA: <https://www.niaaa.nih.gov/alcohols-effects-health/alcohol-topics/alcohol-facts-and-statistics/alcohol-treatment-united-states>