MEDIA RELEASE

Kinoxis awarded new US grant funding to support clinical development of KNX100 for opioid use disorder

- *KNX100 is a small molecule in development for the treatment of substance use disorders, including symptoms associated with withdrawal from opioids*
- *US$3.6 million awarded to Kinoxis under the US National Institutes of Health National Institute on Drug Abuse's UH3 program to fund Phase 1 clinical development of KNX100*
- *Phase 1 clinical trial in progress and due for completion Q3 2023*
- *Phase 2 trials to be backed by Series B funding round*
- *KNX100 is one of a small number of novel molecular entities in active clinical development for treating opioid use disorder worldwide*

MELBOURNE, AUSTRALIA, 8 June 2023. Kinoxis Therapeutics is pleased to announce it has been awarded a UH3 grant by the National Institute on Drug Abuse (NIDA), part of the US National Institutes of Health (NIH), which is expected to provide approximately US$3.6 million over 3 years. The grant will be applied to funding the Phase 1 clinical development of Kinoxis' lead molecule, KNX100, for the treatment of symptoms associated with withdrawal in patients with opioid use disorder.

Kinoxis is a private, Australian based, clinical stage company developing novel therapeutics for substance use, neurological, and psychiatric disorders. This new funding was secured after the company successfully completed the milestones defined in an earlier, UG3 grant received from NIDA in 2019 under the US Federal Government's Helping to End Addiction Long-term Initiative, or NIH HEAL Initiative.

Opioid use disorder is a crisis with major public health implications and overdose deaths involving opioids have claimed the lives of more than half a million people since 1999[1]. In the 12 months to December 2022, more than 105,000 people in the United States died of a drug overdose, with 75% of those deaths involving an opioid, according to recent data from the US Centers for Disease Control and Prevention (CDC)[2]. These harrowing statistics reflect the scale of the crisis and the need for new treatments to address opioid withdrawal. KNX100 is currently one of only a small number of novel molecular entities in active clinical development for the treatment of opioid use disorder globally.

"Opioid use disorder is a major and worsening problem in the US and many other countries. New treatment options are needed for managing withdrawal symptoms and helping people to recover from opioid addiction." said Hugh Alsop, co-founder and CEO of Kinoxis Therapeutics.

"We have an investigational therapy with significant potential in KNX100. The progression of our NIDA grant to the UH3 phase is an important milestone for Kinoxis as it represents further, significant external validation of the KNX100 program and provides the capital required to study key clinical safety endpoints."

In February 2022 Kinoxis achieved clearance from the US Food and Drug Administration for an Investigational New Drug application for KNX100. The company has commenced a Phase 1, first in human clinical study which is in progress at Nucleus Network in Melbourne, Australia. The double blind, placebo controlled, randomized study is investigating the safety, tolerability, and pharmacokinetics of repeat daily administration of KNX100 in healthy volunteers. The Phase 1 study is expected to be completed in Q3 2023.

"To-date we've demonstrated KNX100 reduces opioid withdrawal symptoms in preclinical models through highly disease relevant actions in the brain and have now progressed to testing in humans with our Phase 1 safety study," said Associate Professor Michael Bowen, co-founder and Chief Scientific Officer of Kinoxis Therapeutics. "We're excited to continue working with NIDA on the clinical development of KNX100 for the treatment of opioid use disorder," he concluded.

KNX100 is an oral, small molecule drug candidate in capsule form, with a novel mechanism of action which targets key brain regions critical to regulating withdrawal and addictive behaviors. Promising data has been obtained to date, demonstrating effects on drug withdrawal, consumption and relapse in preclinical models of opioid, cocaine, methamphetamine, nicotine, and alcohol use disorders. KNX100 has also shown considerable promise in preclinical models of agitation and aggression.

Kinoxis is backed by Uniseed, Australia's longest running venture fund, and a consortium of sophisticated investors. The company has recently commenced a Series B financing round, which aims to raise up to A$16 million to fund three Phase 2 clinical trials for KNX100, in opioid withdrawal, methamphetamine use disorder, and the treatment of agitation and aggression in dementia patients.

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About Opioid Use Disorder

Opioids are drugs widely used in the medical management of pain due to their analgesic effects, that are also commonly misused or used illicitly due to their powerful rewarding and addictive properties. Opioids suppress activity in parts of the brain that control breathing and for this reason carry a significant risk of fatal overdose. Opioid use disorder occurs when an individual using opioids, either recreationally or as part of pain management, develops a problematic pattern of use that causes significant problems or distress.

Despite the enormity of the problem, only a limited number of FDA approved pharmacological treatment options are currently available and these are underutilized, with only 22% of people in the USA with opioid use disorder (OUD) receiving an OUD-specific treatment[3]. Overcoming the severe opioid withdrawal syndrome that emerges soon after ceasing or reducing opioid use is the first major barrier to recovery. Opioid withdrawal is characterized by severe psychological disturbances, such as anxiety and craving, and physical symptoms, such as nausea, increased heart rate, and muscle spasms. Kinoxis' KNX100 program aims to help tackle the opioid epidemic by providing a safer, more effective treatment for the mitigation of opioid withdrawal symptoms.

About Kinoxis

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 effective treatments for substance use disorders and social dysfunction in neurological and psychiatric conditions. Kinoxis' development candidates are novel, small molecules that were discovered through a comprehensive medicinal chemistry program at the University of Sydney.

The company is backed by Uniseed, Australia's longest running venture fund, and a consortium of sophisticated investors. In addition to this private funding, Kinoxis has secured significant funding from the US National Institutes of Health National Institute on Drug Abuse for the development of its lead compound to mitigate opioid withdrawal symptoms.

Kinoxis has recently entered into a strategic partnership and licensing agreement with Boehringer Ingelheim, for the development of oxytocin-targeting precision psychiatry treatments to improve the quality of life of people living with neuropsychiatric disorders.

Learn more at www.kinoxistherapeutics.com.

Investors / partners, please contact:

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3. https://www.samhsa.gov/data/release/2021-national-survey-drug-use-and-health-nsduh-releases