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UNIVERSITY OF SYDNEY EXECUTES SITE AGREEMENT TO PROGRESS PHASE II CLINICAL TRIAL INTO ALCOHOL USE DISORDER

Woke Pharmaceuticals is pleased to announce that Sydney Local Health District (SLHD) has approved a site-specific assessment and executed a site agreement with the University of Sydney, as part of progressing a Phase II clinical trial exploring the efficacy of Woke's high-dose formulation of synthetic psilocybin (WP002) to treat Alcohol Use Disorder (AUD).

Considered a brain disorder, AUD can occur with different levels of severity but is characterised by an impaired ability to stop or control alcohol use despite potentially negative social, occupational, or health consequences.

According to the World Health Organisation (WHO) an estimated 400 million people, or 7% of the world's population aged 15 years and older, lived with alcohol use disorders. Of this, 209 million people (3.7% of the adult world population) lived with alcohol dependence.

New strategies for treating AUD are urgently needed according to the University of Sydney. Recent studies have shown promising results for psychedelic-assisted therapies, particularly psilocybin, supporting efficacy in reducing alcohol consumption and improving psychological well-being.

The University of Sydney will conduct a double-blind, randomised controlled trial with 60 participants diagnosed with AUD. The primary aim is to compare the efficacy of psilocybin-assisted therapy (two sessions of psilocybin, 25 mg per dosing session) versus control (niacin 250mg) and therapy in reducing alcohol consumption, specifically measuring the number of heavy drinking days (HDD) per week.

The study also plans to compare the efficacy of psilocybin-assisted therapy versus control in improving the characteristics of AUD and addressing common comorbidities associated with AUD, including depression and anxiety.

The Managing Director of Woke Pharmaceuticals, Matthew Hayne said, "Alcohol Use Disorder is a major global health issue that has negatively affected the lives of hundreds of millions of people across the world. As a brain disorder, we have high hopes that Woke's high-dose formulation of synthetic psilocybin combined with therapy will show promise in treating this condition.

"Our company is currently preparing a strategy to transport WP002 to the research team as we expect patient recruitment to begin shortly.

"As the first trial of its type in Australia and one of the first in the world, we expect there will be a great deal of interest in the findings from the world-renowned research team led by Professor Paul Haber AM and Professor Kirsten Morley of University of Sydney School of Medicine," said Matthew Hayne.

Mr Hayne said that 2025 has been a transformative year for Woke Pharmaceuticals, "The development and patent filings surrounding the discovery of new LSD analogues with the University of Western Australia, progression of the world's largest microdosing trial of synthetic psilocybin at Macquarie University and now the beginning of an innovative clinical trial into Alcohol Use Disorder with one of the world's most regarded Universities, all mark major milestones for our company and speak to the strength and diversity of the Woke Pharmaceuticals business."



The University of Sydney led study is listed on ClinicalTrials.gov with ID NCT06444243 and can be viewed here <https://clinicaltrials.gov/study/NCT06444243>.

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ABOUT WOKE PHARMACEUTICALS

Woke Pharmaceuticals Pty Ltd is an Australian-based company focused on the development and commercialisation of novel psychedelic therapies for the treatment of mental health disorders. The Company's lead candidates are based on synthetic psilocybin, which is a naturally occurring psychedelic prodrug compound produced by more than 200 species of fungi. Clinical trials have shown its safety and efficacy in the treatment of mental health disorders. Woke Pharmaceuticals is developing two dose forms with rapid release capabilities. The Company is also conducting a novel drug discovery programme to identify pharmacologically optimised analogues of LSD with The University of Western Australia.

For further information, please visit www.wokeph.com.