

## PRESS RELEASE

# Woke and University of Sydney Sign Clinical Trial Agreement for Phase IIB trial of WP002 Psilocybin in Alcohol Use Disorder

- Woke Pharmaceuticals and the University of Sydney sign clinical trial research agreement for a Phase IIB trial in alcohol use disorder
- Proposed Phase IIB trial of Woke's WP002 novel psilocybin tablet with psychotherapy in approximately 60 patients
- Professor Paul Haber at the University of Sydney, a leading researcher in the field of addiction medicine, will be the Principal Investigator

**12 December 2022 – Woke Pharmaceuticals Pty Ltd** ('Woke' or 'the Company'), a Sydney NSW-based company focused on psychedelics for mental health, and the University of Sydney today announced that they have progressed from a previously signed term sheet to entering a clinical trial agreement to conduct a randomised controlled Phase IIB trial of WP002 (psilocybin) in patients with Alcohol Use Disorder ('AUD') (the 'Trial').

Under the terms of the agreement, Woke will support the Trial (financially and by providing WP002 and placebo). Professor Paul Haber and Associate Professor Kirsten Morley from the University's Faculty of Medicine and Health will design and lead the conduct of the Trial. Subject to ethics approval, the Trial intends to enrol approximately 60 patients to examine safety, tolerability, and proof-of-concept efficacy.

Psilocybin is a naturally occurring psychedelic pro-drug produced by more than 200 fungi. When used at a high dose in combination with psychotherapy, a previous proof-of-concept study of ten participants indicated that psilocybin may be effective for the treatment of patients with alcohol dependence<sup>1</sup>. WP002 is a novel tablet formulation of synthetic psilocybin with enhanced solubility and stability.

Alcohol has a major impact on public health. Alcohol misuse leads to a large burden of disease, including cardiovascular diseases, mental health conditions, digestive diseases, cancer, and injuries. World-wide, approximately 3.8% of all deaths and 4.6% of disability-adjusted life-years are attributable to alcohol. By 2030, alcohol use disorder is estimated to be the fourth leading cause of disability in high-income countries<sup>2</sup>.

The principal investigator of the proposed Trial, Professor Haber AM, is the Clinical Director for Drug Health Services, Royal Prince Alfred Hospital and Head of Specialty of Addiction Medicine, Sydney Medical School, at the University. Professors Haber and Morley have led numerous clinical studies for the treatment of substance use disorders and are also leading the methylenedioxymethamphetamine (MDMA)-assisted psychotherapy trial to treat patients with combined alcohol and post-traumatic stress disorder.

Professor Paul Haber from the University of Sydney said: "We urgently need to develop new and effective ways to help people with alcohol problems. We are excited to build on the early evidence that psilocybin may be a step forward in treatment through this trial."

Mr Nick Woolf, CEO of Woke Pharmaceuticals, commented: "We are delighted to have finalised the clinical trial agreement with the University of Sydney to evaluate the potential of our WP002 psilocybin drug candidate to treat alcohol use disorder. This disorder affects a vast number of people with limited treatment options. We believe that WP002 with psychotherapy could offer a new treatment option and durable benefit to patients. We look forward to commencing this trial with Professor Haber and A/Professor Morley, given their knowledge of this disorder and experience in conducting trials of psychedelic-assisted psychotherapy."

1. MP Bogenschutz et al. 2015. Psilocybin-assisted treatment for alcohol dependence: a proof-of-concept study. *Journal of Psychopharmacology*. 29(3):289-99
2. C Buntrock et al. 2022. Reducing problematic alcohol use in employees: economic evaluation of guided and unguided web-based interventions alongside a three-arm randomized controlled trial. *Journal of Addiction*. 117(3): 611-622



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### ENDS

This announcement was authorised for release by the Directors of Woke Pharmaceuticals.

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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](http://www.wokeph.com).

**ABOUT THE UNIVERSITY OF SYDNEY**

The University of Sydney is one of the world's leading, comprehensive research and teaching universities. We offer an exceptional range of disciplines – more than 400 areas of study – and our community includes more than 70,000 students, 8000 permanent and fixed-term staff and 350,000 alumni in more than 170 countries.

Leadership has always been at the core of our values. We were one of the first universities in the world to admit students solely on academic merit, and to open our doors to women on the same basis as men. Our aim is to make lives better not just by producing leaders of society, but through equipping our people with the qualities that allow them to serve all our communities at every level.

In creating the first university in Australia in 1850, our founders recognised the power of education to inspire positive change. We hold that belief just as strongly today.

Currently ranked 4th in the world in the QS Graduate Employability Rankings and 41st in the QS World University Rankings, the University of Sydney is also consistently placed among the top universities in the world.

**ABOUT WP002**

WP002 is designed to address the challenges and limitations of oral psilocybin. WP002 is a physically modified form of crystalline psilocybin in a tablet, developed in collaboration with Monash University's Medicines Manufacturing Innovation Centre. It has the potential to provide faster onset of action, reduce time and resource burden on patients and providers, and improve stability (shelf life).