



## PRESS RELEASE

# Woke Collaborates with Monash University to Develop Novel Psilocybin Formulation for Moderate Depression

### Highlights

- Research agreement with Monash University's Medicines Manufacturing Innovation Centre
- Novel low-dose psilocybin formulation for treatment of moderate depression
- Supports planned Phase IIB trial commencing in H2 CY2022 at Macquarie University

**19 October 2021 – Woke Pharmaceuticals Pty Ltd** ('Woke' or 'the Company'), a Sydney NSW-based company focused on psychedelics for mental health, is pleased to announce that it has entered into a research collaboration with Monash University's Medicines Manufacturing Innovation Centre ('MMIC') to develop a novel low dosage form of psilocybin, WP001, for the treatment of moderate depression.

Psilocybin is a naturally occurring psychedelic pro-drug produced by more than 200 fungi. When used at a sub-hallucinogenic dose, or at a higher dose in combination with psychotherapy, it has been shown to be effective for the treatment of patients with depression and other mental health disorders. Woke and MMIC will be formulating a synthetic version of psilocybin into a novel capsule that modifies the release profile of the drug when ingested and improves the stability of the final product.

Woke plans to initiate a Phase IIB trial of WP001 in H2 CY2022 in patients with moderate depression at Macquarie University NSW. This randomised, placebo-controlled study will be the first of its kind with psilocybin. The primary endpoint will be the Grid-Hamilton depression score but will also include secondary endpoints that will evaluate biomarkers, as well as neurophysiological and physiological measures.

Mr Nick Woolf, CEO of Woke Pharmaceuticals, commented: "I am delighted to collaborate with the team at Monash University's MMIC. They have exceptional insights regarding formulation of novel dosage forms of active drugs such as psilocybin. With this collaboration underway, we are well placed to achieve our objective of commencing a seminal Phase IIB trial at Macquarie University that addresses the unmet need of patients with moderate depression."

Professor Michelle McIntosh at Monash University and Director of MMIC, said: "The MMIC team is excited by this opportunity to partner with Woke Pharmaceuticals and provide services that could lead to a novel treatment for patients suffering from depression. Woke Pharmaceuticals is seeking to pioneer novel psychedelic formulations for the treatment of mental health and we look forward to working with them on this project."

**ENDS**

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

### For more information, please contact:

Mr Nick Woolf  
CEO  
info@wokeph.com  
+61 417 986 005

### 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 for the treatment of depression. Psilocybin



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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 depression and other disorders. Woke Pharmaceuticals is developing a novel micro-dose formulation for treatment of moderate depression and a novel high-dose formulation with concomitant psychotherapy for treatment of major depression. Both candidates are expected to enter Phase II trials in 2022 with leading investigators in the field of mental health. For further information, please visit [www.wokeph.com](http://www.wokeph.com).

**The Medicines Manufacturing Innovation Centre** is an initiative between the Victorian State Government and Monash Institute of Pharmaceutical Sciences (MIPS), based on a proven model of success between Monash University and GSK. The Centre has a focus on growing exports of medicines manufactured in Victoria and supports pharmaceutical manufacturers and allied industries by facilitating the optimisation of processes, current and new product development and building supply of highly skilled, industry-ready, workforce candidates. MMIC provides clients with access to world-class infrastructure and a multidisciplinary team to deliver economic impact and competitiveness.