

14 April 2025

MACQUARIE UNIVERSITY MICRODEP TRIAL SET TO ENTER NEXT PHASE OF RESEARCH

Woke Pharmaceuticals is pleased to announce that Macquarie University is about to complete the Vanguard Stage of its Phase IIB trial aiming to test the efficacy of Woke's low-dose formulation of synthetic psilocybin (WP001) to treat moderate depression.

The research team led by Dr Vince Polito, one of the world's foremost experts in microdosing, is pleased with the outcomes to date as the drug candidate had been extremely well tolerated, with no notable acute adverse reactions reported.

These positive outcomes follow the screening of over 300 individuals and 250 dosing sessions of 24 individuals.

Dr Polito said that he was delighted to have reached the end of the Vanguard Stage of the project, "The MicroDep Trial is progressing extremely well. We've established and are delivering a highly ambitious treatment protocol involving clinical, psychometric, cognitive, biomarker, neuroimaging and performance-based measures.

"I'm very happy with the outcomes so far. We have maintained high levels of participant safety and care. Our treatment approach has been well tolerated, and exit interviews indicate high rates of acceptability and feasibility of the trial. Our internal systems are very well developed, and we are ready to progress to the main intervention stage of the project," said Dr Vince Polito.

This Phase IIB trial is a randomised, double blind, placebo-controlled study with a target enrolment of 240 patients suffering from depression of moderate severity. This is a highly rigorous and well powered design that will comprehensively assess the impact of WP001 on mental health.

The Vanguard Stage included two visits from independent monitors, with the trial passing both audits.

The Managing Director of Woke Pharmaceuticals, Matthew Hayne said, "The MicroDep Trial is the largest psilocybin-based trial focusing on microdosing in the world. The main stage of the trial will now test the efficacy of our drug candidate against placebo.

"The results of this phase will eventually be published by the research team and will be closely followed and reviewed. Essentially, we will receive an early indication as to whether our unique drug candidate holds strong promise and merits a final Phase III clinical trial, which is typically the last stage before a drug is reviewed for registration as an approved medicine.

"We thank Dr Polito and his team for their work so far. Our hope is that Woke's low-dose formulation will provide a viable treatment option for sufferers of moderate depression in the years to come," said Matthew Hayne.

In the United States, a 2019 survey by the National Centre for Health Statistics showed that 15.7 percent of respondents had reported suffering from mild to moderate depression in the last two weeks from the day surveyed.

The MicroDep Trial Steering Committee is made up of leading psychedelic, mental health and clinical trial researchers from across Australia. Members of the team are:



WOKE PHARMACEUTICALS
HEALING THROUGH PSYCHEDELIC THERAPIES

Chief Principal Investigator
Dr Vince Polito
Macquarie University

Principal Investigator (Medical)
Dr Jonathan Brett
St Vincents Hospital, Sydney / Macquarie University

Principal Investigator
Dr Adam Bayes
The Black Dog Institute, University of New South Wales

Principal Investigator
Professor Anthony Rodgers
The George Institute

Principal Investigator
Dr Paul Liknaitzky
Monash University

Principal Investigator
Professor Richard Stevenson
Macquarie University

Principal Investigator (Psychiatrist)
Dr Joanne Shannon
Macquarie University

ENDS

For more information, please contact:

Mr Matthew Hayne
Managing Director
matt@wokeph.com

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.