

20 June 2024

MACQUARIE UNIVERSITY RECRUITS FIRST PATIENTS FOR AUSTRALIA'S LARGEST PSYCHEDELIC FOCUSED CLINICAL TRIAL

Woke Pharmaceuticals, investor into the largest and most diverse portfolio of psychedelic research projects in Australia, is pleased to announce that Macquarie University has made strong progress in its clinical trial aiming to test the efficacy of Woke's low-dose formulation of synthetic psilocybin (WP001) to treat moderate depression.

According to the World Health Organization (WHO), an estimated 5 per cent of the world's population suffers from depression.

Under the leadership of Dr Vince Polito, one of the world's foremost experts in microdosing, Macquarie University has begun screening patients for the Vanguard Phase of the trial which aims to explore the safety and feasibility of the proposed broader trial. So far 9 patients have been randomised into the trial with a further 16 candidates expected to be recruited by year's end to complete this stage.

Preceding this, the team at Macquarie University received ethics approval for the trial, clinical governance approval, and approval from New South Wales Health to possess and supply a scheduled drug.

Dr Polito believes that the trial may produce interim data as soon as Quarter One, 2025.

"Our team is incredibly excited for this trial to be underway. We have assembled a fantastic research team and are now well established in the world class facilities of Macquarie University Hospital," said Vince Polito, Chief Investigator of the MicroDep Trial.

"This trial is the first large scale, longitudinal study of the effects of low doses of psilocybin in a clinical population. Participants will complete an innovative and comprehensive battery of clinical, behavioural, and physiological measures that will significantly push forward our understanding of the effects of microdosing."

As part of the trial, people will participate in a series of real-world activities to test their basic functionality while under the influence of a microdose. As an example, trial participants will utilise a driving simulator at Macquarie University so that researchers can test whether Woke's low dose formulation impairs their driving skills and if so, to what extent.

This Phase IIB trial will have one clinical trial site in Sydney and is a randomised, double blind, placebo-controlled study with a target enrolment of 266 patients suffering from depression of moderate severity. This trial structure is seen as the 'gold standard' in medical research.

Patients will receive 11 doses of WP001 over a six-week intervention period. The primary outcome measure will be the industry-standard GRID-Hamilton Depression Rating Scale. Secondary outcomes will include psychological measures, neurophysiological measures, and omics-based biomarkers.

The Macquarie trial is Australia's largest psychedelic clinical trial and is also believed to be the largest psilocybin-based trial focusing on microdosing in the world. It is also Australia's first controlled microdosing study.

“While not discounting the terrible impacts of severe depression (which Woke is exploring and looking to treat in other clinical trials), most people suffering from depression generally experience mild to moderate depression. This condition can still be very debilitating. People can often experience enhanced anxiety and anger and/or turn to other harmful substances to help get through these periods,” said Matthew Hayne, Managing Director of Woke Pharmaceuticals.

“Users of low dose psilocybin have often reported enhancements in mood and creativity. Typically, users report experiencing no hallucinatory effects from microdosing and psilocybin is known to be a non-addictive substance.”

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.

“We are very excited to see whether Woke’s low dose formulation of synthetic psilocybin could prove helpful to people suffering from moderate depression. If so and while there would be many more steps in a process to getting a drug to market, people in the future could potentially have access to a non-addictive mood enhancer to help them get through tough periods in their life,” said Matthew Hayne.

“While there remains a long way to go in this process, we are delighted by the progress that Dr Polito and his team have made at Macquarie and look forward to updating our shareholders on the trial’s progress as the year progresses,” concluded Matthew Hayne.

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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.