

PRESS RELEASE

Woke Enters Clinical Agreement with QIMR Berghofer to Evaluate WP002 Psilocybin for Prolonged Grief

Highlights

- Woke Pharmaceuticals and QIMR Berghofer enter clinical trial agreement for treatment of prolonged grief
- Innovative, investigator-initiated Phase II clinical trial of Woke's WP002 novel psilocybin tablet with psychotherapy in approximately 15 patients
- Trial protocol has been submitted for ethics approval and could commence enrolment in early CY2023

19 December 2022 – 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 a Clinical Trial Research Agreement with QIMR Berghofer to conduct a Phase II trial of Woke's novel rapid release tablet of psilocybin, WP002. The trial will evaluate the feasibility, safety and initial impression of efficacy of WP002 alongside psychotherapy for the treatment of patients with prolonged grief.

Psilocybin is a naturally occurring psychedelic pro-drug produced by more than 200 fungi. When used at a high dose in combination with psychotherapy, psilocybin has been shown to be safe and effective as a treatment for mental health and related disorders. WP002 is a novel tablet formulation of synthetic psilocybin with enhanced solubility and stability.

Under this Agreement, Woke will provide its WP002 clinical material, as well as funding that is partially matched by a grant from QIMR Berghofer. The study will inform further development, including the design of larger randomised controlled studies.

The study, named PARTING: Psilocybin-Assisted supportive psychoTherapy IN the treatment of prolonged Grief, will enrol approximately 15 patients with the intention of demonstrating recruitment feasibility, intervention acceptability, safety and proof-of-concept efficacy.

The trial has been submitted for approval by the QIMR Berghofer Human Research Ethics Committee. Recruitment is expected to commence in the first half of 2023. Bereaved carers of people with cancer who meet the criteria for prolonged grief disorder will be invited to take part in PARTING. Potential participants will undergo rigorous screening before enrolment to meet general medicine and psychiatric eligibility criteria. The intervention will include three preparatory psychotherapy sessions, one psilocybin dosing session and six post-experience psychotherapy integration sessions.

While grief is a normal reaction to loss, 30% of cancer carers are reported to experience prolonged grief disorder. Patients with prolonged grief require grief-focused intervention in addition to the depression-focused treatment. Psilocybin-assisted psychotherapy could reduce grief-related distress and suffering.

The principal investigator of the proposed trial, Associate Professor Vanessa Beesley, is the Team Head of the Supportive Care in Cancer Group at QIMR Berghofer Medical Research Institute and is a founding member of the [Queensland Collaborative for Cancer Survivorship](#) which focuses on developing and evaluating health innovations. She has developed a translational program of work assessing real world implementation of a nation-wide support service with Australia's leading [pancreatic cancer organisation](#) for families faced with and bereaved by pancreatic cancer. Her other work focuses are on patients and families affected by ovarian cancer and parents of children with cancer.

Associate Professor Vanessa Beesley has worked with bereaved carers and seen the devastation and trauma that can sometimes linger and cause significant troubles in people's lives. She commented: "We are delighted to be working with Woke Pharmaceuticals on this feasibility trial of a novel intervention regimen. There is an unmet need for new approaches to treat prolonged grief particularly in cancer carers. Psilocybin-assisted psychotherapy has shown to be beneficial in previous studies for the treatment

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of related mental health disorders. Our team includes leading scientists from around Australia with expertise in psycho-oncology, psychiatry, and psychedelic medicine. This open-label trial of Woke's WP002 psilocybin drug candidate with psychotherapy will provide information about the intervention acceptability and a qualitative initial impression of efficacy. As a secondary analysis of potential efficacy, we will also explore changes in grief scores."

Mr Nick Woolf, CEO of Woke Pharmaceuticals, said: "We are pleased to have entered this clinical trial agreement with QIMR Berghofer which expands the potential indications of our WP002 rapid release psilocybin tablet to include prolonged grief. This disorder affects a vast number of people with limited treatment options. We believe that WP002 psilocybin-assisted psychotherapy could offer a new treatment option and durable benefit to people with this condition. Associate Professor Beesley and her team have extensive knowledge and experience in this field. We look forward to commencing the trial."

The commencement of recruitment for the trial will be announced by QIMR Berghofer in coming months.

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.

ABOUT QIMR BERGHOFFER

QIMR Berghofer is a world-leading, translational medical research institute that seeks to discover, diagnose and deliver better treatments for some of the world's deadliest and most debilitating diseases. Every day, the Brisbane institute's team of 1,000 scientists, support staff, and students lives out a mission to achieve better health through medical research, focusing on the fields of cancer, inflammation, infection, population health, mental health, and neuroscience. Translating discoveries from bench to bedside and progressing research from hopeful theory to daily reality, they are saving lives.

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).