

Woke and QIMR Berghofer Sign Letter of Intent for Clinical Trial of WP002 Psilocybin in Prolonged Grief

- Woke Pharmaceuticals and QIMR Berghofer sign Letter of Intent for clinical trial in prolonged grief
- Proposed clinical trial of Woke's WP002 novel psilocybin tablet with psychotherapy in approximately 15 patients
- Associate Professor Vanessa Beesley, Principal Investigator at QIMR Berghofer, is a leading researcher in the field of a behavioural science and supportive care in cancer research

12 August 2022 – Woke Pharmaceuticals Pty Ltd ('Woke' or 'the Company'), a Sydney NSW-based company focused on psychedelics for mental health and QIMR Berghofer Medical Research Institute ('QIMR Berghofer') have signed a Letter of Intent to conduct a clinical trial of WP002 (psilocybin) in patients with prolonged grief. The trial is in the final stages of design, and it is expected patient recruitment will commence in early 2023.

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 depression, anxiety and substance abuse. WP002 is a novel tablet formulation of synthetic psilocybin with enhanced solubility and stability.

Under this Letter of Intent, Woke is working with Associate Professor Vanessa Beesley who will design and conduct an open-label clinical trial of WP002 in patients with prolonged grief disorder. 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 and proof-of-concept efficacy.

When recruitment commences in 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: "There is an unmet need for novel approaches to treat prolonged grief particularly in cancer carers. Psilocybin-assisted psychotherapy has shown to be beneficial in previous studies for the treatment of related mental health disorders and therefore I have put together a team of leading scientists from around Australia with expertise in psycho-oncology, psychiatry, and psychedelic medicine to design a new intervention to address this need. Our intention with Woke is to conduct an open-label trial of Woke's



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WP002 psilocybin drug candidate with psychotherapy to provide information about 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 be in exclusive discussions with QIMR Berghofer to expand the potential indications of our WP002 psilocybin drug candidate 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 aim to finalise an agreement within the next few weeks with the institute to support this exciting 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 for the treatment of depression. Psilocybin 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. The Company is also embarking on 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 BERGHOFER

QIMR Berghofer is a world-leading, translational medical research institute that seeks to discover, diagnosis and deliver better treatments for some of the world’s deadliest and most debilitating diseases. Every day, the Brisbane institute’s team of 1000 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.