

PRESS RELEASE

Woke Welcomes Psilocybin Down-Scheduling

Highlights

- Therapeutic Goods Administration (TGA) to down-schedule psilocybin for treatment-resistant depression (TRD) from Schedule 9 to Schedule 8
- Under the re-scheduling, specialist psychiatrists approved by ethics and authorised by the TGA can prescribe psilocybin to treat TRD from 1 July 2023
- Woke's WP002 psilocybin drug candidate, commencing Phase II development for TRD, will be available for patients under the TGA's Authorised Prescriber Scheme

6 February 2023 – Woke Pharmaceuticals Pty Ltd ('Woke' or 'the Company'), a Sydney NSW-based company focused on psychedelics for mental health, welcomes the decision of the Therapeutic Goods Administration (TGA) to down-schedule psilocybin from Schedule 9 to Schedule 8 for treatment-resistant depression (TRD).

Under the re-scheduling, from 1 July 2023, psilocybin can be prescribed in Australia for TRD by specialist psychiatrists who have approval from a Human Research Ethics Committee (HREC) and have been authorised under the TGA's Authorised Prescriber Scheme. There are currently no products containing psilocybin included in the Australian Register of Therapeutic Goods (ARTG) that have been evaluated by the TGA for safety, quality and efficacy. However, the TGA stated that there is sufficient evidence that psilocybin will potentially be effective in the treatment of TRD for certain patients.

Psilocybin is a naturally occurring psychedelic pro-drug produced by more than 200 fungi. When used at a high dose in combination with psychotherapy, clinical data suggests that psilocybin is safe and effective for treating TRD.

Woke is developing WP002, a novel tablet formulation of synthetic psilocybin, with enhanced solubility and stability, manufactured in Australia in accordance with Good Manufacturing Practices. Woke's primary goal is to register WP002 on the ARTG by conducting rigorous clinical research. The Company is commencing a randomised controlled Phase II trial of WP002 in 160 patients with TRD. The trial is being conducted by Swinburne University in collaboration with Monash University and University of Tasmania. Enrolment is expected to commence in mid-2023.

Following the TGA's decision to down-schedule psilocybin, the Company is planning an educational initiative for specialist psychiatrists regarding psilocybin and its use for TRD. Authorised Prescribers are healthcare practitioners who have authorisation from the TGA to prescribe specific products for specific medical conditions. Woke's WP002 psilocybin tablet will be made available to Authorised Prescribers in accordance with the TGA's requirements from 1 July 2023.

Mr Nick Woolf, CEO of Woke Pharmaceuticals, said: "The down-scheduling of psilocybin for treatment-resistant depression demonstrates the TGA's commitment to novel treatment approaches. In their statement, the TGA referred to the relative safety and potential efficacy of psilocybin when used in a medically controlled setting. Woke is developing a novel psilocybin drug candidate, WP002, for treatment-resistant depression and other mental health disorders. We welcome this decision by the TGA and plan to educate specialist psychiatrists so that psilocybin will be prescribed safely and effectively to patients with this debilitating disorder."

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 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 and manufactured under GMP by IDT Australia. It has the potential to provide faster onset of action, reduce time and resource burden on patients and medical practitioners, and improve stability (shelf life).