



PRESS RELEASE

Woke's Response to TGA Decision to Maintain the Current Schedule 9 Classification for Psilocybin

- TGA confirms its interim decision not to amend the current Schedule 9 classification with respect to psilocybin
- TGA acknowledged that the safety profile of psilocybin has been established and that initial studies have shown potential for treatment of depression
- This decision does not impact Woke Pharmaceuticals' plans to commence Phase IIb trials of psilocybin in H2 CY2022

17 December 2021 – Woke Pharmaceuticals Pty Ltd ('Woke' or 'the Company'), a Sydney NSW-based company focused on psychedelics for mental health, responds to the TGA's decision not to amend the Schedule 9 classification of psilocybin.

In making its decision, the TGA acknowledged that psilocybin showed potential for the treatment of treatment-resistant depression when administered in closely supervised settings and with intensive support. The TGA concluded that psilocybin may show promise in highly selected populations but only where these medicines are administered in clinically supervised settings and with professional support.

Furthermore, the TGA noted that their decision does not affect current access to psilocybin for use in a clinical trial setting under Schedule 9. The outcomes of further clinical trials could result in there being more supportive evidence in the future. Down-scheduling could be further considered if there were more evidence of therapeutic value from such clinical trials. The provisions for clinical trials of psilocybin are unchanged with approval of Commonwealth and/or State or Territory health authorities.

The comments from the TGA support Woke's objective to conduct rigorous clinical trials of psilocybin for the treatment of depression, both at a low dose for moderate depression and at a high dose for treatment-resistant depression. Woke has established a supply chain for formulation and manufacture of its novel psilocybin dosage forms with partners in the US and Australia who have relevant licences and permits for Schedule 9 products.

Mr Nick Woolf, CEO of Woke Pharmaceuticals, said: "The TGA is seeking further clinical evidence that supports the therapeutic value of psilocybin and outweighs the risks of potential misuse. We agree with this premise and are at the forefront of generating robust data from two planned Phase IIb trials of psilocybin, conducted in Australia, for the treatment of depression. The results of these trials could inform a future application for the down-scheduling of psilocybin."

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. For further information, please visit www.wokeph.com.