



## Media Alert: 26 September 2023 – Melbourne, Australia

### [New Overseas Trial Results Strongly Support the TGA’s Decision to Reschedule the controlled Use of MDMA and Psilocybin for Mental Illness](#)

On 3<sup>rd</sup> February 2023 the TGA announced the restricted rescheduling of MDMA and Psilocybin as Schedule 8 Controlled Medicines when used as part of therapy for patients with post-traumatic stress disorder (MDMA) or treatment resistant Depression (psilocybin). As part of the [decision](#) the TGA acknowledged the current lack of treatment options for patients suffering from these mental illnesses which can cause immense suffering.

The TGA’s decision was based on a wealth of evidence presented by Mind Medicine Australia in its rescheduling [applications](#) as well as on the TGA’s own investigations and feedback from over thirteen thousand public submissions. These submissions were 98% in favour of the rescheduling and included thousands of positive submissions lodged by clinicians and researchers.

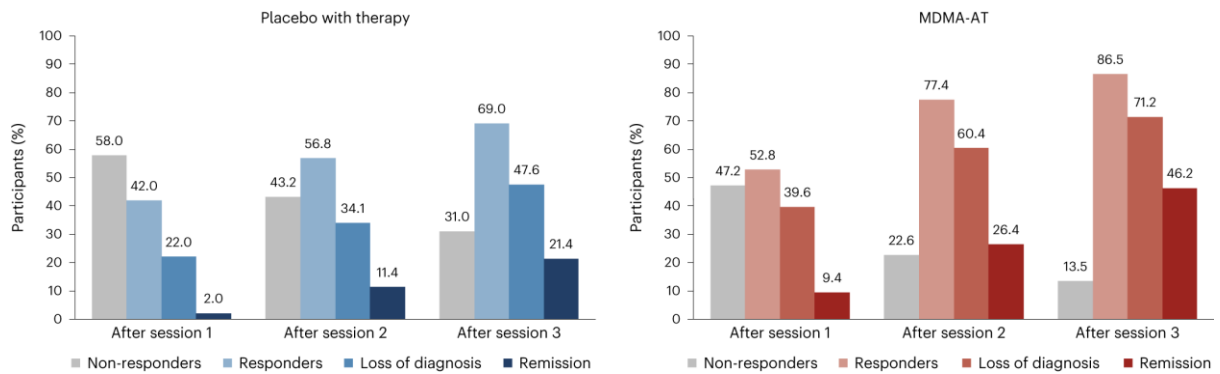
It is therefore highly relevant that two major trials, which have just published their results in leading medical journals, provide further support for the use of these medicines in the controlled conditions envisaged by the TGA.

The trial sponsors in each case were not for profit organisations focused on the alleviation of suffering and both had successfully obtained **Breakthrough Therapy Status** from the FDA in the United States to fast-track the assessment of these medicines because of their enormous potential.

1. **[The MAPS Second Stage Phase 3 Trial Report “MDMA-assisted therapy for moderate to severe PTSD: a randomised placebo-controlled phase 3 trial” published in Nature Medicine on 14 September 2023](#)**

This multi-site trial confirmed the impressive results of the MAPS first stage Phase 3 trial and the MAPS Phase 2 trials. In particular, following the treatment with MDMA assisted therapy:

- **86.2%** of participants in the MDMA group noted improved symptoms compared to **69%** in the placebo group.
- **71.2%** of participants in the MDMA group also no longer met the criteria for PTSD versus **47.6%** in the placebo group.
- Participants in both groups were drawn from ethnically diverse backgrounds, indicating the broader generalisability of the treatment.
- Covariate analyses demonstrated similar responses to treatment regardless of disease severity, risk of hazardous alcohol or substance use disorder, severe adverse childhood experiences or dissociative subtype PTSD.
- Reported side effects of the treatment, including muscle tightness and nausea, were in line with expectations. There were no serious treatment emergent adverse effects or challenges such as suicidal ideation.



**Table 1 reproduced from Fig 3 of the Nature Medicine Article showing the treatment response and remission rates of participants in the MDMA assisted therapy and placebo plus therapy groups.**

Sample sizes for both of the MAPS Phase 3 trials were developed with guidance from the FDA to ensure adequate and rigorous testing of outcomes during the trial period.

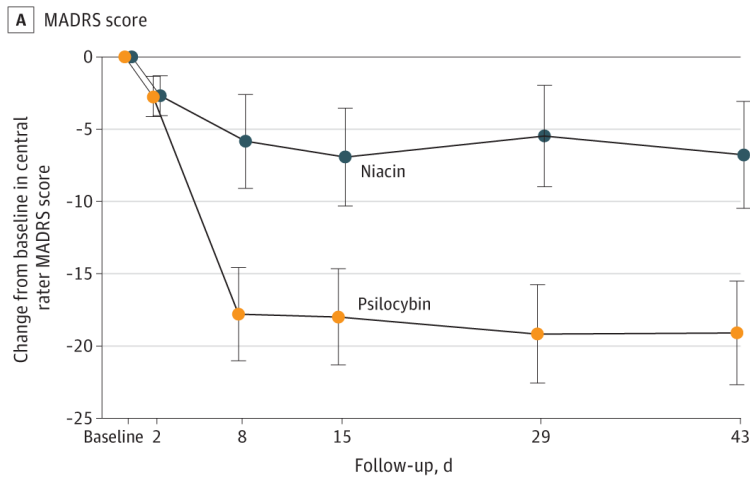
MAPS has indicated that it will be lodging an application later this year for MDMA to be registered as a medicine in the United States when used as part of therapy. The TGA's rescheduling decision is more limited and only applies to the use of MDMA as an unregistered medicine.

**2. The Usona Institute Phase 2 Trial: "Single - Dose Psilocybin Treatment for Major Depressive Disorder" published in JAMA 31 August 2023.**

This large multi-site, randomised, multi-blinded, placebo-controlled trial was designed to evaluate the magnitude, timing and durability of antidepressant effects and safety of a single dose of psilocybin combined with therapy in patients with major depressive disorder. The trial followed the successful Compass Pathways trial using a single dose of psilocybin for treatment resistant depression [published](#) in **The New England Journal of Medicine** on 3 November 2022.

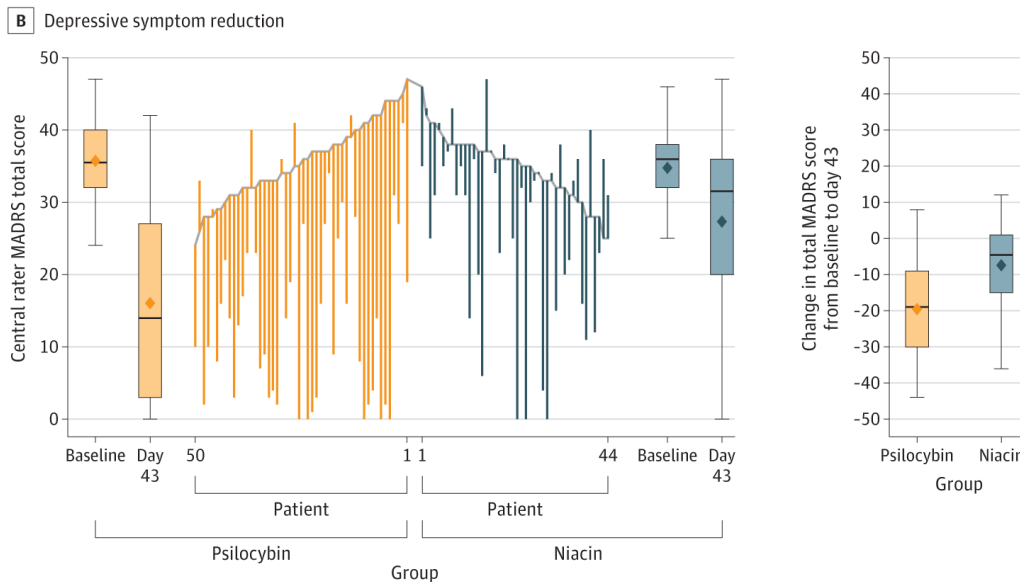
The research conclusions were that the psilocybin administered with psychological support was associated with a rapid and sustained antidepressant effect, measured as a change in depressive symptom scores, compared with the active placebo group. Psilocybin was generally well tolerated and there were no serious treatment emergent adverse effects in the psilocybin group.

Importantly, the treatment with psilocybin didn't cause any emotional blunting which can be a side effect of antidepressant use for some patients.



No. of participants at risk

Psilocybin	51	51	51	50	49	50
Niacin	53	52	50	45	44	44



**Table 2 reproduced from Fig 2 of the JAMA Article showing changes in Montgomery-Asberg Depression Rating Scale (MADRS) score of participants in the psilocybin and placebo groups.**

According to the Chair of Mind Medicine Australia, **Mr Peter Hunt AM**: “These results further demonstrate why the TGA’s rescheduling decision is so important for patients suffering from PTSD or from treatment resistant Depression. These are debilitating illnesses which can cause immense suffering. The challenge now is to make sure that government controls don’t unreasonably restrict patient access.”

According to the Executive Director of Mind Medicine Australia, **Tania de Jong AM**: “We now will be able to collate Real World Evidence about the application of these therapies in clinical practice through the [registry](#) specifically set up for this purpose by the Australian National University. This is a World first. The controlled clinical application of these therapies to help



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*patients suffering from debilitating conditions doesn't preclude ongoing clinical trials which Mind Medicine Australia is also strongly supporting."*

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Mind Medicine Australia is Australia's leading not-for-profit organisation working on the use of medicinal psilocybin and MDMA-assisted therapies to treat a range of mental illnesses. Mind Medicine Australia exists to help alleviate the suffering and suicides caused by our accelerating mental illness epidemic in Australia, through expanding the treatment options available to medical practitioners and their patients.

Visit: <https://mindmedicineaustralia.org/>

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