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Subject: MAPS Phase 3 Trial Results
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Attachments: [ATT00001.png](#)
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[ATT00003.gif](#)

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Dear Ben

Happy new year!

MAPS recently completed the second Phase 3 trial of the use of MDMA assisted therapy for post- traumatic stress disorder (PTSD) and we have been waiting for an announcement of the results. As you will recall, the results for the first Phase 3 trial published in Nature Medicine last year were stunning. Not only did 67% of the participants in the MDMA group go immediately into remission but a further 21% experienced a clinically meaningful reduction in symptoms. In addition, adverse events were low and manageable in the MDMA group but worse in the placebo group. No treatments currently in use achieve anything like these results (indeed the evidence suggests that remission rates using current treatments are less than 10%).

MAPS have just made a preliminary announcement of their second Phase 3 trial results – see the following link - [Prior Positive Results Confirmed in MAPS-Sponsored, Philanthropy-Funded Phase 3 Trial - Multidisciplinary Association for Psychedelic Studies - MAPS](#)

As you will see MAPS has announced that the second Phase 3 trial results confirm the first Phase 3 trial results. Specific comments in the announcement are:

“MAPP2, the second Phase 3 trial of MDMA-assisted therapy, treated 104 participants living with PTSD with either MDMA-assisted therapy or placebo with therapy”

“ The results confirmed findings from MAPP1; no serious adverse events were observed among the participants”

“The full data from MAPP2, expected to be published in a peer-review journal later this year, will support MAPS PBC’s new drug application to be filed with the US Food and Drug Administration”.

These results again emphasise why the medical use of MDMA as part of therapy, in the conservative manner proposed in our rescheduling application, should be rescheduled to Schedule 8 of the Poisons Standard. If this doesn’t happen the TGA will basically be saying that the regimen for unregistered medicines permitted by the Poisons Standard for some reason doesn’t apply to the medical use of MDMA. Given the abuse (and deaths) associated with the medical use of opiates - which are far more dangerous than the medical use of MDMA as part of therapy - this would be an extraordinary and perverse outcome.

As already discussed, we’d like to organise a presentation from experts focusing on the medical

use of psilocybin and MDMA as part of therapy and why they satisfy the Schedule 8 tests. Too many people are committing suicide in Australia (including ADF veterans and First Responders) and suffering terribly for this not to happen.

I hope this is helpful.

With best wishes

Peter

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