# SAS-B Application Cover Letter

DATE

Contact person: INSERT NAME OF PSYCHIARTRIST AND/ OR GENERAL PRACTITIONER/PHYSICIAN QUALIFICATIONS

Medicine name: Psilocybin

Indication: Major Depressive Disorder (MDD)/Treatment-Resistant Depression (TRD)

Attached Documents

1. Curriculum Vitae of applicant
2. SAS-B Application Form
3. Patient consent form
4. Treatment protocol overview
5. FDA approved psilocybin for MDD/TRD Phase 2 protocol
6. References

To Whom it May Concern,

This submission is an application to prescribe psilocybin for the treatment of MMD/TRD in combination with psychotherapy under the Special-Access Scheme Category B. Psilocybin-assisted psychotherapy gained US Food and Drug Administration (FDA) ‘Breakthrough Therapy Designation’ in 2019 for MDD and 2018 for TRD due to results of research trials.

I myself, have consulted with Mind Medicine Australia in regards to specific education around the safe and effective provision of psilocybin along-side psychotherapy, specifically for MMD/TRD.

**EXAMPLE:** The reason for this application is to address the desperate need of my at-risk patient XX, in the opinion of their medical team, have exhausted clinically appropriate treatment options within RACGP and best practice guidelines. The consequence of not having found a helpful treatment results in; increasing disability for XX, deteriorating social and family integration as well as increasing health system costs.

There are a variety of pharmacotherapy treatment options for depression, those currently available include, selective-serotonin reuptake inhibitors (SSRIs), selective-norepinephrine reuptake inhibitors (SNRIs), monoamine oxides inhibitors (MAOIs), tricyclic antidepressants, and some antipsychotics. Despite this, of those entering treatment, only 35% of patients experience any clinical improvement in their depression symptoms from the above medications. This figure is significantly less for remission.

Psilocybin-assisted psychotherapy is emerging as a promising treatment for MMD/TRD internationally, research is now progressing to Phase 2 internationally. The treatment involves in-clinic administration of medicinal psilocybin alongside psychotherapy and has been found to lead to complete remission in 60-80% of patients in recent significant Phase 2 clinical trials. These patients suffered from depression because of a life-threatening cancer diagnosis. Across the Phase 2 study there was no dropout, demonstrating high tolerability and patient adherence. Most side-effects/adverse-reactions were rated mild to moderate (blood pressure, heart rate, anxiety, fearfulness, derealisation, paranoid thinking, yawning, nausea, vomiting, tearing, crying, open and closed eye visuals, spontaneous motor reaction, restlessness, fidgetiness, psychological and physical discomfort) and there were no unexpected psilocybin-related adverse events within these trials. Psilocybin has been shown to be non-addictive and non-toxic at doses used in clinical research trials. Doses well above these have been shown to also be non-addictive and non-toxic.

Psilocybin reduces the activity of a brain network called the Default Mode Network (DMN), (an area of functional connectivity). The DMN is associated with rumination about the past, daydreaming, autobiography, and is known to be tightly correlated, or overactive, in several mental illness. By temporarily decoupling the activity of the DMN, psilocybin appears to enable communication among more diverse brain regions. In this way, psilocybin may facilitate a more plastic, receptive brain state. This hypothesis, along with the downstream proposed effects of 5-HT2A receptors, accounts for the importance of the environment or therapeutic context ). Integration occurs in a window after treatment where the patient is more open to change.

The advanced provision of psilocybin-assisted therapy has been granted under the FDA’s ‘Expanded Access Scheme’ in the US. Australia would be following the international lead by making psilocybin-assisted therapy available for at-risk patients.

The authorised provision of psilocybin-assisted psychotherapy under Special Access Scheme Category B would include:

* Adherence to guidelines and protocols as specified in the FDA approved Phase 2 treatment protocols
* One active session dose of psilocybin in an in-clinic session with the set and setting (SaS) protocol of psychotherapy across 6-8 hours for each patient.

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| **Patient Weight** | **Dose** |
| <90kg | 25mg |
| 90-115kg | 30mg |
| >115kg | 35mg |

* SaS protocol will be utilised similar to the protocol that has been used in all modern studies of psilocybin. The SaS protocol for SAS-B includes: 1) a period of preparation with session Facilitators prior to dosing; 2) administration of study medications in an aesthetically pleasing room under the supervision of two Facilitators who are present throughout the session; and 3) three post-dose integration sessions during which participants are encouraged to discuss their intervention experience with the Facilitators.
* The provision of clinical support for this in the form of an appropriately trained psychiatrist and/or general practitioner, physician and/or psychologist, psychotherapist, counsellor, mental health social worker and /or nurse to conduct the psychotherapy in the preparatory, acute and integration sessions.
* Creation of the recommended clinical setting, including adherence to protocols for safety and security and the management of risk.
* Pre- and post-treatment clinical and psychological assessment to enable an evidence-based approach to reporting on outcomes. Including the report of any adverse or unexpected events to the TGA
* Provision of the medication as obtained directly from MAPS, thereby ensuring research-quality standards.
* Appropriate security measures for handling, safekeeping, and administration of a schedule 9 substance.
* Established support and collaboration with MAPS by providing data for inclusion in their study. Data similarly being gathered and processed for inclusion in any future local study.

Thank you for reviewing this application, I look forward to your response.

Yours sincerely,

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