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Developing innovative treatments for
mental health & neurological conditions

ASX Announcement | 10 January 2024

Emyria's Specialist Psychiatrist Granted Authorised Prescriber Status in MDMA-Assisted Therapy for PTSD

HIGHLIGHTS

Emyria's key specialist has been granted "Authorised Prescriber" approval from the TGA

Authorisation reflects Emyria's dedication to mental health care under strict regulatory, ethical, and safety standards

Achieving Authorised Prescriber status for MDMA-assisted therapy in PTSD care signifies a strategic step towards expanding Emyria's service offerings

Emyria Limited (ASX: EMD) ("Emyria", or the "Company") focused on delivering and developing new treatments for mental health and select neurological conditions, is pleased to announce the Company's distinguished psychiatry specialist has been granted "Authorised Prescriber" status by the Therapeutic Goods Administration (TGA). The authorisation enables the prescribing of MDMA according to an ethics committee endorsed care model developed by Emyria [1] and within the strict regulatory framework established by the TGA for the treatment of Post-Traumatic Stress Disorder (PTSD). [2]

Dr. Michael Winlo, CEO and MD, commented: *"This authorisation demonstrates Emyria's commitment to evaluating emerging treatments within the strict regulatory framework set by the TGA.*

Emyria's expertise and track record in innovative clinical service development and Real-World Data capture uniquely positions us to evaluate new therapeutic options in a safe and responsible way. Achieving Authorised Prescriber status showcases Emyria's capacity for impactful and responsible growth in the field of mental health treatments."

Initial focus on Post-Traumatic Stress Disorder (PTSD):
PTSD affects approximately 1 million Australians [3]. With up to one third of patients failing to benefit from conventional therapies, there is a growing need for more effective treatments. MDMA-assisted therapy (MDMA-AT) is being evaluated as a treatment for PTSD and multiple Phase 3 clinical trials have been conducted by MAPS in the USA. [4, 5]

Emyria is currently studying MDMA-AT therapy for PTSD in an ethics-approved clinical trial (EMDMA-001). Experience with the trial has informed a unique delivery model for Emyria's Authorised Prescriber program.

Authorised Prescribers must adhere to stringent TGA guidelines to ensure the highest level of patient care and safety. The authorisation is part of Emyria's broader commitment to increasing options for mental health through robust clinical research and ethical practice.

A presentation explaining how the Authorised Prescriber milestone fits into Emyria's broader strategy will be available on the ASX platform.

Risks associated with the use of MDMA

All medicines carry risks and specialist prescribers, such as registered psychiatrists, are best placed to assess the suitability of a new medication against a patient's individual circumstances and medical history before proceeding. Adverse effects of MDMA include high blood pressure, increased pulse rate, faintness, and panic attacks, and in some rare cases it can cause loss of consciousness or trigger seizures. Other side effects include involuntary jaw clenching, decreased appetite, restless legs, nausea, headache, sweating and muscle/joint stiffness. These effects are unlikely at low doses in the treatment regimens used in psychedelic-assisted psychotherapy while appropriately managed in a controlled environment with direct medical supervision.

References:

1. See ASX release 30 October 2023

2. https://www.tga.gov.au/news/media-releases/change-classification-psilocybin-and-mdma-enable-prescribing-authorised-psychiatrists

   The availability of these products is subject to the safety and efficacy of the products being tested through clinical trials. Emyria makes no representations or warranties as to the safety or efficacy of the products or the products' ability (or the ability of its key compounds) to be used in the treatment of indications such as PTSD. There are currently no approved products containing MDMA that the TGA has evaluated for quality, safety and efficacy. Consumers should be aware that MDMA may cause side effects, as set out in the "Risks associated with the use of MDMA" in this announcement.

3. https://www.phoenixaustralia.org/news/ptsd-awareness-day-2022/

4. Mitchell, J.M., et al. MDMA-assisted therapy for severe PTSD: Nat Med 27, 1025–1033 (2021)

5. Mitchell, J.M., et al. MDMA-assisted therapy for moderate to severe PTSD: Nat Med (2023). https://doi.org/10.1038/s41591-023-02565-4

This release has been approved by the Board of Emyria.

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DELIVERING & *DEVELOPING* NEW TREATMENTS TO IMPROVE MENTAL HEALTH

DELIVER INNOVATIVE CARE: Our clinics offer care programs that comply with current regulatory standards, including treatments involving drugs that have undergone recent rescheduling where clinically justified	**20,000** patients cared for to date (across Emyria's clinical service subsidiaries)
CREATE REVENUE GROWTH: We apply strong commercial discipline to ensure healthy and sustainable service revenues	**$1m / qtr** from clinical services and growing each year (as per Sep Qtr 4C. 2023)
SCALE NATIONALLY, THEN INTERNATIONALLY: We leverage our **revenues** to support capacity growth; We use our **data** to support innovation and IP creation	**30** treatments / month target first yr

FOR FURTHER INFORMATION

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CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS Any statements in this press release about future expectations, plans and prospects for the Company, the Company's strategy, future operations, and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the Company's ability to successfully develop its product candidates and timely complete its planned clinical programs and the Company's ability to obtain marketing approvals for its product candidates. In addition, the forward-looking statements included in this press release represents the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.