

emyria

A clinical stage biotech informed by patient experience.
Tackling unmet needs in neuroscience and mental health.

ASX Announcement | 30 October 2023

Emyria Secures Ethics Endorsement for MDMA Authorised Prescriber Application

HIGHLIGHTS

- Emyria receives endorsement from a National Health and Medical Research Council ('NHMRC') accredited ethics committee in support of Authorised Prescriber ('AP') applications for the lead psychiatrists of its MDMA-assisted therapy ('MDMA-AT') program
- The approval is the first stage of a 2-step evaluation; final approval is still required from Australia's Therapeutic Goods Administration ('TGA') and is in progress
- MDMA-AT for Post-Traumatic Stress Disorder ('PTSD') demonstrated to be effective and safe in second Phase 3 clinical trial published by MAPS last month [1]
- Following active dosing in Emyria's ethics-approved trial [2], the AP endorsement, if secured, may allow Emyria to become one of the first Australian groups to offer broader options for PTSD patients with inadequate relief from conventional care

Emyria Limited (ASX: EMD) ('Emyria', or the 'Company') an integrated clinical drug development and care delivery firm specialising in mental health, neuropsychiatry, and select neurological conditions, is pleased to announce that its lead psychiatrists have received endorsement from an NHMRC-accredited ethics committee, allowing them to advance their Authorised Prescriber applications with the TGA.

Understanding the Authorised Prescriber Designation:
Following the TGA's recent rescheduling of MDMA and psilocybin for PTSD and treatment-resistant depression respectively, the restrictions around their prescribing remain highly stringent due to the lack of "approved" or "registered" versions of these medicines. Consequently, the medicines can only be accessed via clinical trials or from specialist psychiatrists who secure AP status from the TGA. [3]

The requirements for becoming an Authorised Prescriber are strict and mandate that applying specialists first achieve endorsement from either an NHMRC-accredited ethics committee or the Royal Australian and New Zealand College of Psychiatrists ('RANZCP'). This involves the submission and review of an comprehensive care model expected to include supportive psychotherapy and ongoing monitoring. [4, 5]

Once AP status is obtained, these medical practitioners are held to rigorous standards which include staying updated on the medicines, obtaining informed consent, ensuring use of pharmaceutical-grade medicine, patient safety monitoring, regular reporting to the TGA, and full compliance with all relevant state-based legislations.

With ethics committee endorsement, the Company can now progress its AP applications with the TGA for final consideration.

Focus on PTSD and the emerging evidence behind MDMA-AT:
With around 1 million Australians affected by PTSD [6], the need for beneficial and durable treatments is pressing. MDMA-AT has shown promising clinical results in multiple Phase 3 trials by MAPS in the USA and is emerging as a potential new treatment approach.

As part of Emyria's deep commitment to mental health, the Company has been investing in capabilities to both deliver and develop emerging, promising treatments, such as MDMA-AT for PTSD. Recently, Emyria acquired the Pax Centre [7] - a leading multidisciplinary clinical service providing holistic psychological trauma care. This strategic move broadens Emyria's mental health footprint and supports the gathering of Real-World Data with patients.

Emyria's unique data helps inform both the scalable delivery models for interventions like MDMA-AT as well as the Company's extensive novel drug development programs.

Emyria's EMDMA-001 Trial:
Emyria's ethics-approved and active EMDMA-001 trial [2] is expected to generate robust clinical data to support feasibility evaluations, payer engagement as well as Emyria's proprietary drug development programs. The trial also provides Emyria's clinical team with a blueprint for the AP program's rigorous requirements which, if obtained, has the potential to increase Emyria's clinical service offering to a broader patient base, especially those suffering from PTSD..

Emyria's Managing Director, Dr. Michael Winlo, reflected: *"The AP program provides new, but unapproved,, options for patients who have exhausted standard care options. With our history of successfully securing over 16 AP approvals for our clinicians involved in our cannabinoid treatment programs, this ethics-committee endorsement further highlights our dedication to expanding care options for Australian patients."*

References:

1. https://www.nature.com/articles/s41591-023-02565-4
2. See ASX announcement 09 October 2023
3. https://www.tga.gov.au/products/unapproved-therapeutic-goods/mdma-and-psilocybin-hub
4. https://www.tga.gov.au/sites/default/files/2022-12/authorised-prescriber-scheme-221205.pdf
5. https://www.ranzcp.org/clinical-guidelines-publications
6. https://www.beyondblue.org.au/mental-health/anxiety/types-of-anxiety/ptsd
7. See ASX announcement 13 September 2023

This release has been approved by the Managing Director of Emyria.

FOR FURTHER INFORMATION

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Emyria Limited is an integrated clinical services and drug development company focused on revolutionising patient outcomes in mental health and neuroscience via a unique business model:

generates

Emyria Clinics: Deliver evidence-based and emerging therapies for mental health and other unmet needs across multiple sites (Emerald Clinics and The Pax Centre)

Emyria Data: Robust and ethically-sourced Real-World Data gathered with patients and integrated into an advanced data platform powered by Palantir. Emyria data is used to improve Emyria's distinct therapy and drug development programs.

informs

Emyria Drug Discovery: One of the world's largest libraries of unique MDMA-like compounds developed in partnership with the University of Western Australia seeking new psychedelic-assisted therapies and treatments for neurological diseases.
Emyria Drug Development: A suite of unique, highly potent dose forms of Ultra-Pure cannabinoids seeking registration for a range of mental health and neuroscience indications.

EMYRIA'S INTERACTIVE INVESTOR HUB
Investorhub.emyria.com Interact with Emyria's announcements and updates by asking questions and comments, which our team can respond to where possible.

PaxCentre **paxcentre.com.au**

The Pax Centre specialises in treating individuals grappling with the psychological impacts of traumatic experiences. Our treatment approach is highly personalised, addressing a wide range of mental health issues, from PTSD and depression to anxiety disorders and substance abuse, often stemming from various life traumas.

Complex trauma, characterised by repeated, relational traumatic events often occurring during developmental stages, requires specialised attention due to its pervasive and lasting impact. In these cases, The Pax Centre prioritises early diagnosis and evidence-based treatments.

We also focus on proactive strategies for health expansion and personal growth, empowering our clients with skills and tools to improve wellbeing and performance. At the Pax Centre, we believe in transforming lives through focused, evidence-based mental health care.

emerald clinics **emeraldclinics.com.au**

Emerald Clinics is an Australian-based, patient-centric clinical service specialising in providing treatments for patients with complex and chronic conditions, where traditional therapies might not have yielded satisfactory results.

Leveraging our deep expertise with unregistered medicines, such as cannabinoids, we strive to pioneer and personalise care for our patients. Our robust, ethically-sourced data collection methods underpin our commitment to improving patient outcomes and advancing healthcare innovation.

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.