ASX Announcement

26 September 2022

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Emyria expands clinical sites for EMD-RX5 Phase 3 trial

HIGHLIGHTS

Emyria has now qualified 8 clinical trial sites across Australia to support the pivotal Phase 3 trial for EMD-RX5

EMD-RX5 is Emyria's first Ultra-Pure cannabinoid treatment created with a proprietary formulation that improves the delivery of CBD and supports global registration opportunities where exceptional purity is a requirement

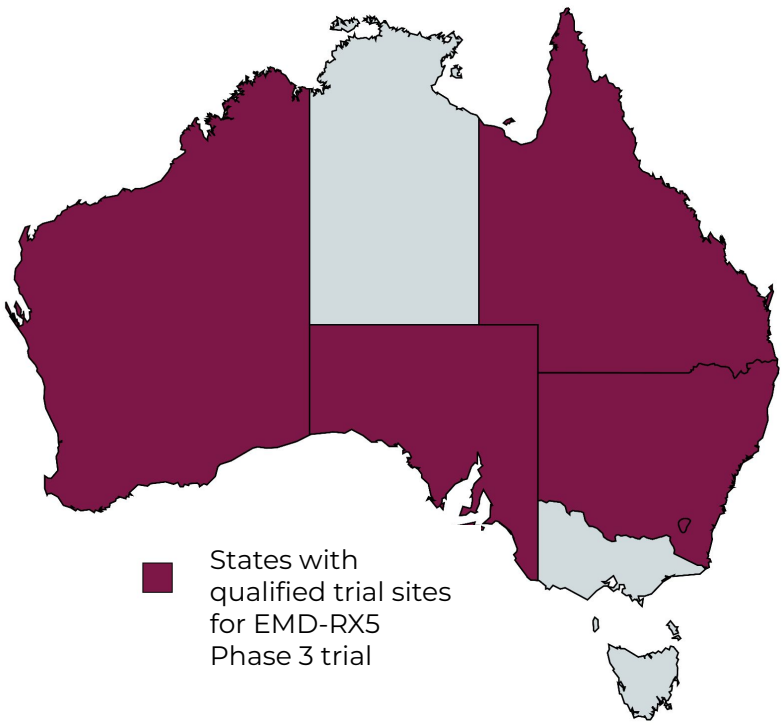
EMD-RX5 has multiple indication potential and is initially seeking registration with the TGA as a Schedule 3, over-the-counter treatment for symptoms of psychological distress

Emyria's Phase 3 clinical trial is now available to patients across Western Australia, Queensland, New South Wales, South Australia and the Australian Capital Territory

Emyria's clinical service subsidiary - Emerald Clinics - will begin accepting expressions of interest for these new sites from September 28th 2022 to support patient recruitment

Emyria Limited (ASX: EMD) (Emyria or the Company), a clinical stage biotech, is pleased to announce it has qualified 8 sites across Australia to support the pivotal Phase 3 clinical trial of EMD-RX5, its first Ultra-Pure cannabinoid treatment. Results from the Phase 3 trial are expected to support an initial registration of EMD-RX5 as a Schedule 3, over-the-counter treatment with Australia's Therapeutic Goods Administration (TGA).

"Qualified" sites have successfully passed extensive feasibility and suitability screens with an independent monitor. Qualified sites are formally approved to participate in core trial activities such as patient recruitment, treatment dosing and clinical assessments. The 8 newly qualified sites join previously activated sites following ethics approval in August *(See ASX release 16 August 2022)*.



Emyria's Managing Director, Dr. Michael Winlo said: *"We have had exceptional demand to participate in our Phase 3 program from clinical sites across Australia. We take this as a strong sign that there is high clinical interest in our unique Ultra-Pure CBD capsule and strong patient need for new treatment options for our target indication - the symptoms of psychological distress.*

8 additional clinical trial sites are now poised to commence patient recruitment across Australia, with our trial drug EMD-RX5 being readied for distribution over the coming weeks. In parallel, we are advancing commercialisation discussions and look forward to providing more updates on the registration of EMD-RX5 in future announcements."

A further 4 sites have been identified for qualification if required. Emyria's nationwide clinical service subsidiary, Emerald Clinics, continues to support patient recruitment.

EMD-RX5 - a unique, Ultra-Pure CBD capsule

EMD-RX5 was developed to overcome many of the limitations with commonly available cannabinoid medicines and has been clinically demonstrated to have excellent safety, tolerability, bioavailability and low patient variability in a head-to-head comparison with the only registered CBD medicine in the world - Epidyolex [1].

EMD-RX5 is a proprietary capsule formulation of Ultra-Pure CBD with the potential to address multiple clinical indications and with the required purity to pursue registration opportunities across multiple major global markets.

Target indication - Psychological distress:

Psychological distress describes a set of mental and physical symptoms such as anxiety, stress, depression, sleep disturbance and gastrointestinal upset that, at any one time, can affect up to 15% of the adult population [2].

Psychological distress has a higher incidence rate in rural patients [3] and patients with chronic disease [4]. Overall the incidence of psychological distress is believed to be increasing. There is currently no over-the-counter treatment for psychological distress.

This announcement has been approved and authorised for release by the CEO of Emyria Limited.

FOR FURTHER INFORMATION

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REFERENCES:

[1] See *ASX release 25 May 2022*
[2] National Study of Mental Health and Wellbeing 2020-21 series, Australian Bureau of Statistics
[3] Kilkkinen et al. Prevalence of psychological distress, anxiety and depression in rural communities in Australia. Aust J Rural Health. 2007 Apr;15(2):114-9. doi: 10.1111/j.1440-1584.2007.00863.x.

Key Phase 3 information:

Study design, product and participant details:

A multi-site, parallel-arm, randomised, double blind, placebo-controlled study to investigate the effect of EMD-RX5 on symptoms of psychological distress in adults with chronic pain.

300 participants aged 18-70 with symptoms of stress and a background of chronic pain will be randomised to one month of treatment with either 50mg EMD-RX5, 150mg EMD-RX5 or matching placebo.

Primary endpoint:

To determine the effect of EMD-RX5 treatment on symptoms of psychological distress in participants with chronic pain through change in self-reported DASS-21 score from baseline to Week 4.

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UPCOMING
DRUG DEVELOPMENT MILESTONES

CLINICAL PROGRAMS
Ultra-pure cannabinoid delivery platform

EMD-RX5
"direct-to-consumer" program

- **Formulation optimisation** ✓
- **Phase 1** ✓
- **Ethics** submitted for Phase 3 ✓
- **Phase 3** commencement ✓
- Regulatory submission
- Commercial strategy **Australia**
- Commercial strategy **Europe**
- Commercial strategy **USA**

EMD-RX7
"prescription medicine" program

- **Formulation optimisation** ✓
- **Phase 1**
- Pre-IND **(FDA)**
- **Pivotal** trials

PRE-CLINICAL PROGRAM
MDMA-like analogues

MDMA-like drug development

- **Screening results** for first 85 compounds ✓
- **First patent family** filed ✓
- Batch **3** sent ✓
- Batch 3 **screening results** ✓
- **Create and screen** additional batches ✓
- **US-focussed** preclinical program ✓
- **Metabolic** studies ✓
- **Preclinical assays** *(multiple animal models)* ✓
- **Human cell** line assays ✓
- **Lead** selection
- **Phase 1** trials

ABOUT EMYRIA | emyria.com

Emyria Limited is a clinical drug development and care delivery company focused on accelerating drug development and improving patient outcomes via:

- **Drug Development:** Emyria has developed an Ultra-Pure cannabinoid platform that can support the registration of multiple proprietary dose forms. Emyria's first dose form, EMD-RX5 is in Phase 3 trials
- **New Drug Discovery:** Inspired by MDMA, Emyria is developing one of the world's largest libraries of MDMA-like compounds with partner, the University of Western Australia.
- **Proprietary Real-World Data (RWD):** Emyria gathers ethically-sourced data with patients cared for at Emyria's own specialist clinical service (Emerald Clinics). Emyria RWD can help support drug development and care model improvement.

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.

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.