ASX Announcement
30 Jan 2023

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

First dosing commenced for pivotal EMD-RX5 Phase 3 trial

HIGHLIGHTS

Emyria has commenced first dosing for the pivotal Phase 3 clinical trial of lead candidate EMD-RX5 - a proprietary, solid capsule formulation of Ultra-Pure CBD targeting registration as one of the first Over-The-Counter CBD medications with Australia's TGA

9 clinical trial sites activated nationwide, trial expected to enrol 300 patients in total

Over 200 patients now pre-screened, with rate of patient dosing expected to increase due to significant early engagement and ongoing support from Emerald Clinics.

Multiple comparative advantages to Emyria's over-the-counter registration program:

- EMD-RX5 is a proprietary, solid capsule of Ultra-Pure CBD without THC or impurities
- EMD-RX5 has demonstrated high bioavailability in Phase 1 trials
- Emyria is testing up to 150mg CBD/day - the maximum allowable dose for OTC
- Emyria is only company targeting the symptoms of psychological distress - a condition affecting 15% of the Australian adult population with no OTC treatment available [1]

Emyria Limited (ASX: EMD) (Emyria or the Company), a clinical stage biotech, is pleased to announce that the first patients have been successfully dosed in its Phase 3 clinical trial for EMD-RX5. This marks an important milestone in the development of EMD-RX5 as the first potential over-the-counter (OTC) treatment for the symptoms of psychological distress.

The trial, which is being conducted nationwide across 9 trial sites, is designed to evaluate the safety and efficacy of EMD-RX5 in patients with symptoms of psychological distress such as mild anxiety and stress. The trial is expected to enrol and dose 300 patients in H1, 2023 and, pending clinically significant results, will support a submission to the TGA.

Emyria's Managing Director, Dr Michael Winlo said: *"An accessible, convenient and effective over-the-counter treatment for psychological distress could have a significant impact on the quality of life and health outcomes for patients, especially those with chronic disease.*

We believe EMD-RX5 represents a significant commercial opportunity as it has been uniquely formulated to meet the registration requirements of multiple global markets,. The need for mental health treatments is large and growing, and an over-the-counter option could support a large segment of the population alongside prescription medication and non-drug therapy. "

[1] Australian Institute of Health and Welfare 2018. Australia's health 2018. Australia's health series no. 16. AUS 221.

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EMD-RX PLATFORM COMPARATIVE **ADVANTAGES**

EMD-RX5
Solid capsule

Vs

CBD Oils
& similar preparations

		EMD-RX5	CBD Oils
	Dose form	Convenient, **solid oral capsule** *(no spilling)*	Majority **oil preparations**
	Active pharmaceutical	**Ultra-Pure CBD (synthetic)** - **No detectable** *THC* - **No detectable** *impurities*	**Plant-derived CBD:** - **Small quantities of** *THC* & *impurities*
PRODUCT	Safety & Tolerability	**Safe & well tolerated** at trial doses **No observed** gastrointestinal upset	**Adverse events at higher doses** *(eg GI upset)*
PRODUCT	Intellectual property	**Proprietary** formulation	Most CBD oils **"me too" products** with generic formulations and limited IP protections
	Drug exposure profile	**High** bioavailability, **low inter-patient** variability **& slow release** [1]	**Poor** bioavailability**, high patient** variability [2]
	Cost of Goods	Ultra-Pure CBD has **lower costs of goods** supporting lower out-of-pocket prices for patients	Plant based CBD currently ranges in cost from $225-800/month for 150mg CBD / day dosing [3]
	Environmental impact	**Ultra-Pure CBD produces 44x less CO2 and uses 333x less water** compared to plant-based CBD [4]	
REG STRATEGY	FDA-readiness	**Ultra-Pure CBD** has **FDA Drug Master File** therefore suitable for FDA registration [5] *Allows Emyria to reference material to regulator without disclosing contents of formulation*	Only one product registered with FDA but needed to achieve "small molecule" (Epidiolex) **FDA moving to regulate CBD industry** [6]
REG STRATEGY	Indication selection	Informed by analysis of **Emyria's proprietary Real World Data** (over 8,000 patients)	Most Australian competitors pursuing "sleep disturbance", an indication where clinical endpoints have not been met to date [7] [8]

1. See ASX release 25 May 2022
2. https://www.tga.gov.au/sites/default/files/review-safety-low-dose-cannabidiol.pdf
3. https://honahlee.com.au/articles/medical-marijuana-cost-australia/#prices
4. Zheng, Z., Fiddes, K. & Yang, L. A narrative review on environmental impacts of cannabis cultivation. J Cannabis Res 3, 35 (2021). https://doi.org/10.1186/s42238-021-00090-0
5. www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs
6. https://www.fda.gov/news-events/press-announcements/fda-concludes-existing-regulatory-frameworks-foods-and-supplements-are-not-appropriate-cannabidiol
7. https://www.cannabiz.com.au/blow-for-cann-group-as-over-the-counter-cbd-trial-fails-to-show-efficacy-for-sleep-disturbance/
8. https://www.cannabiz.com.au/ecofibre-acquires-hemp-brand-soul-seed-and-ploughs-ahead-with-sleep-focused-s3-trial/

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.

Patient registration: https://trials.evrima.com/stress-anxiety-medical-study

"An accessible, convenient and effective over-the-counter treatment for psychological distress could have a significant impact on the quality of life and health outcomes for patients, especially those with chronic disease."
- **Emyria's Managing Director, Dr Michael Winlo**

- This release has been approved by the Board of Emyria. -

FOR FURTHER INFORMATION

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UPCOMING DRUG DEVELOPMENT MILESTONES

DRUG DEVELOPMENT

CLINICAL PROGRAMS
Ultra-Pure cannabinoid delivery platform

EMD-RX5 *"direct-to-consumer"*
Formulation optimisation ✓
Phase 1 study ✓
Ethics approved for Phase 3 ✓
Phase 3 commencement ✓
Regulatory submission
Commercial strategy **Australia**
Commercial strategy **Europe**
Commercial strategy **USA**

EMD-RX7 *"prescription medicine"*
Formulation optimisation ✓
Phase 1
Pre-IND **(FDA)**
Pivotal trials

NEW DRUG DISCOVERY

PRE-CLINICAL PROGRAM
MDMA-like analogues

MDMA-like drug development
Continuous creation & screening ✓
First patent family filed ✓
US-focused preclinical program ✓
Metabolic studies ✓
Preclinical assays *(multiple animal models)* ✓
Human cell line assays ✓
Advanced assay development
Lead selection
Phase 1 trials
Global commercial strategy

ABOUT EMYRIA | emyria.com

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

- **Drug Development:** Emyria is developing multiple, proprietary, Ultra-Pure cannabinoid dose forms suitable for registration against multiple indications. 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 robust and 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
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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.