ASX Announcement

16 Aug 2022

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Emyria receives ethics approval for pivotal EMD-RX5 Phase 3 trial; Patient recruitment to commence

Highlights:

- Emyria has received Human Research Ethics Committee (HREC) approval to commence a pivotal Phase 3 clinical trial of its first Ultra-Pure CBD candidate, EMD-RX5
- Emyria has completed all necessary safety and efficacy evaluations of EMD-RX5 and will now commence recruitment with Clinitrials, supported by Emyria's clinical service subsidiary, Emerald Clinics
- The Phase 3 trial design was informed by Emyria's proprietary Real World Data and will assess the safety and efficacy of two dose strengths of EMD-RX5 to improve the symptoms of psychological distress in patients with a background of chronic pain
- EMD-RX5 is a proprietary formulation of Ultra-Pure CBD that meets the quality standards of both the TGA and FDA in order to support multiple registration programs globally

Emyria Limited (ASX: EMD) (Emyria or the Company), a clinical stage biotech, is pleased to announce it has received Human Research Ethics Committee (HREC) approval to commence a pivotal Phase 3 clinical trial of its Ultra-Pure CBD candidate, EMD-RX5.

Successful completion of the Phase 3 trial will support the registration of EMD-RX5 with the Therapeutic Goods Administration (TGA) as a schedule 3, over-the-counter treatment (OTC) for the symptoms of psychological distress.

The study's primary endpoints are changes in validated psychological distress symptom scores. Secondary endpoints include validated measures of sleep, pain and other quality of life scores.

The Phase 3 trial is a multi-center, double-blind, randomised, placebo-controlled trial and will be conducted under Australia's Clinical Trials Notification (CTN) Scheme. This means Emyria will now notify the TGA of HREC approval and complete local site initiation activities. The first site to receive ethics approval is the Hatherley Medical Centre under the direction of Principal Investigator Dr Zachary Nathan.

Additional clinical sites will be opened and managed across Australia by leading Site Management Organisation, Clinitrials. Emyria's clinical service subsidiary, Emerald Clinics, will assist with patient recruitment for the study. *(See ASX announcement 12 April 2022)*

Emyria's Managing Director, Dr. Michael Winlo said: *"The commencement of our pivotal Phase 3 trial is a significant milestone for Emyria and for the many patients managing symptoms of psychological distress but without a registered over-the-counter treatment option.*

We believe a successfully registered OTC medicine in this category represents a large opportunity for Emyria to address a major unmet health need. .

We look forward to further evaluating EMD-RX5 for other indications and registration opportunities while we continue to expand our Ultra-Pure cannabinoid product portfolio, advance our MDMA-inspired drug discovery program and pursue commercialisation opportunities."

Psychological distress describes a collection of symptoms that may comprise mild anxiety, stress, sleep disturbance and gastrointestinal upset. It affects up to 11% of all Australian adults with a higher prevalence in patients living with chronic disease. .[1] There is currently no approved treatment for psychological distress.

EMD-RX5 recently completed a Phase 1 pharmacokinetic (PK) crossover study with Epidyolex®, the only TGA and FDA registered CBD medicine. This study revealed, EMD-RX5 delivers:

- **excellent safety and tolerability** with no gastrointestinal upset or adverse events of concern at test dose of 150mg
- **equivalent bioavailability** and **lower drug exposure variability**
- **higher CBD exposures 3 to 8 hours after dosing**, indicating EMD-RX5 provides more predictable drug exposure over time; suited for non-acute indications and supporting a preferred once to twice daily dosing regime

(See ASX announcement 25 May 2022)

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

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References:

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

Key study 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.

Study conducted according to ICH-GCP guidelines.

Investigational product prepared according to Good Manufacturing Practice (GMP) standards and made by Altasciences, Philadelphia.

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.

Site details:
Clinitrials will act as Site Management Organisation for multiple sites. First site to commence is:
Hatherley Medical Centre
Suite 1/52 Hatherley Parade
Winthrop WA 6150

Principal Investigator:
Dr. Zachary Nathan

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UPCOMING DRUG DEVELOPMENT MILESTONES

CLINICAL PROGRAMS
Repurposing "ultra-pure" cannabinoids

PRE-CLINICAL PROGRAM

EMD-RX5 *"direct-to-consumer"* program	**EMD-RX7** *"prescription medicine"* program	**MDMA**-inspired drug development
Formulation optimisation ✓	**Formulation optimisation** ✓	**Screening results** for first 85 compounds ✓
Phase 1 ✓	**Phase 1**	**First patent family** filed ✓
Ethics submitted for Phase 3 ✓	Pre-IND **(FDA)**	Batch **3** sent ✓
Phase 3 commencement ✓	**Pivotal** trials	Batch 3 **screening results**
Regulatory submission		**Create and screen** additional batches
Commercial strategy **Australia**		**Metabolic** studies ✓
Commercial strategy **Europe**		**Preclinical assays** *(multiple animal models)*
Commercial strategy **USA**		**Human cell** line assays ✓
		Lead selection
		Phase 1 trials

ABOUT EMYRIA | emyria.com

Emyria Limited is a clinical stage biotech focussed on accelerating treatment development and improving patient care by:

1. **Collecting and analysing Real-World Data (RWD):** Emyria gathers ethically-sourced clinical evidence with patients across Emyria's independent clinical services *(emeraldclinics.com.au)*. Emyria's proprietary RWD provides deep treatment and drug development insights.
2. **Repurposing promising treatments:** Emyria uses its RWD to improve the formulations of, and find new indications for, select medications. Emyria's first repurposed and proprietary drug products (EMD-RX5 and EMD-RX7) incorporate Ultra-Pure cannabinoids and are targeting global registration opportunities as over-the-counter and prescription-only medicines.
3. **Developing analogues of promising new compounds**: Emyria collaborates with leading institutions to develop new chemical entities inspired by promising molecules. Emyria's first new chemical entity program is focussed on generating novel MDMA-inspired analogues with the potential to become registered therapies for a range of major unmet needs.

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.
