ASX Announcement
24 Apr 2023

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

Emyria introduces highest potency EMD-RX9 Ultra-Pure CBD capsule; Targeting FDA registration pathways

HIGHLIGHTS

Emyria introduces EMD-RX9, a high potency, highly bioavailable Ultra-Pure CBD capsule following the conclusion of new dose optimisation and dissolution studies on Emyria's expanded, proprietary formulations

EMD-RX9 follows the **recent commercialisation success of Emyria's low-dose CBD capsule, EMD-RX5, with Aspen Pharmacare Australia** [1]

EMD-RX9 is an advanced formulation capable of holding >150mg CBD / capsule and will underpin Emyria's global clinical development plans targeting prescription-based registrations

Emyria is advancing a comprehensive EMD-RX9 USA registration strategy comprising FDA Pre-IND (Investigational New Drug) preparations and head-to-head Phase 1 clinical trials with Epidyolex, planned for H2 2023

Emyria's participation in the NIH's Preclinical Screening Program for Pain (PSPP) to contribute crucial preclinical data for EMD-RX9 and support US-focused registration efforts [2]

Emyria Limited (ASX: EMD), (Emyria or the Company) a clinical stage biotech company is pleased to announce the addition of a high potency, highly bioavailable Ultra-Pure CBD dose form to its proprietary cannabinoid medicine pipeline, EMD-RX9.

The development of EMD-RX9 follows a series of successful studies conducted over the last two quarters to further optimise Emyria's formulations to increase potency. EMD-RX9 builds on the success of Emyria's current lower dose strength capsules, EMD-RX5 and EMD-RX7, which are both 50mg/dose, but will contain over 150mg of Ultra-Pure CBD in each small and easy to swallow capsule. EMD-RX9's proprietary formulation is also expected to have enhanced bioavailability thereby delivering relatively higher CBD dose exposures compared to equivalent oil-based alternatives.

EMD-RX9 is targeting new and existing prescription indications with FDA where high CBD dose exposures are clinically indicated. EMD-RX9 offers competitive advantages in the Company's US-focused registration strategy by addressing the needs of patients who require a high CBD dose but who prefer the convenience and tolerability advantages of a solid oral capsule dose over existing liquid oil alternatives. By ensuring patients can receive maximum potency and effectiveness from each capsule, EMD-RX9 should be able to provide large CBD doses without requiring a patient to swallow a high number of capsules thereby reducing "pill burden".

1. See ASX release 04 April 2023
2. See ASX release 28 November 2022

Emyria CEO, Dr. Michael Winlo, said, *"The launch of EMD-RX9 builds on the recent commercialisation success of our low-dose CBD capsule, EMD-RX5 targeting the over-the-counter market. The higher dose strength and potency of EMD-RX9 will support Emyria's US-focused registration programs by helping address the needs of patients requiring high CBD doses.*

We are confident EMD-RX9 will demonstrate superior bioavailability compared to Epidyolex oil based on earlier head-to-head preclinical PK studies performed with EMD-RX7 and, together with our Real-World Data insights, can help Emyria's growing Ultra-Pure cannabinoid product pipeline address the unmet needs of large patient populations."

The launch of EMD-RX9 follows the recent successful partnership with Aspen Australia Pharmacare (Aspen), one of Australia's largest pharmaceutical companies, for the commercialisation of EMD-RX5. Aspen will leverage their unique resources to support the development, registration, distribution, and sales of EMD-RX5 (Schedule 3) across Australia pending successful Phase 3 clinical trials which are due to complete in July 2023. [1]

Emyria is able to strategically select target indications based on clinical insights within its proprietary Real-World Data set on more than 9,000 patients receiving cannabinoid-based medicines. EMD-RX5, currently in advanced Phase 3 clinical trials, is the only Ultra-Pure CBD medication targeting registration as an over-the-counter medication for anxiety and stress.

The Ultra-Pure CBD in EMD-RX9 is lab-created, offering purity, reliability, and cost advantages over plant-derived CBD options. Preferred by major drug regulators like the FDA and EMA, Ultra-Pure CBD enhances EMD-RX9's market potential.

Emyria's strategic approach to developing innovative CBD treatments, combined with its successful commercialisation of EMD-RX5, positions the company well for future growth. EMD-RX9's unique formulation and high potency offer a promising opportunity for investors, as Emyria continues to advance its prescription program and strengthen its presence in the global cannabinoid-based medicine market.

With a significant partnership now established for EMD-RX5, Emyria is in a strong position to build on this success and advance its clinical programs targeting prescription indications. The company's participation in the NIH's Preclinical Screening Programme for Pain (PSPP) will contribute crucial preclinical data to support US-focused registration efforts.

Emyria is planning the next steps in EMD-RX9's clinical development including conducting a Phase 1 head-to-head pharmacokinetic (PK) study against Epidyolex, the only registered CBD medication worldwide. The Phase 1 study will help demonstrate EMD-RX9's relative bioavailability advantages and support Emyria's Pre-IND (Investigational New Drug) meetings in planning. A Pre-IND is a critical step in the US-registration process that can streamline the pathway to further clinical trials and eventual market approval for EMD-RX9.

With these strategic initiatives in place, Emyria is well-positioned to advance EMD-RX9 through the necessary regulatory stages, unlocking new market opportunities and reinforcing the company's commitment to delivering innovative, high-quality cannabinoid-based medicine to patients in need.

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UPCOMING MILESTONES

CLINICAL PROGRAMS

"direct-to-consumer"
Formulation optimisation (RX5) ✓
Phase 1 study done ✓
Phase 3 commencement ✓
Regulatory submission
Commercial strategy **Australia** ✓
Commercial strategy **Europe**
Commercial strategy **USA**

"prescription medicine"
Formulation optimisation (RX7 > RX9) ✓
Preclinical Screening Program for Pain
Phase 1
Pre-IND **(FDA)**
Pivotal trials

PRE-CLINICAL + THERAPY PROGRAMS

New Drug Discovery
Continuous creation & screening ✓
First patent family filed ✓
US-focused preclinical program ✓
Metabolic studies ✓
Lead selection
Phase 1 trials
Global commercial strategy

Psychedelic-assisted therapy
Protocols developed ✓
Clinical partnerships ✓
Real-World Data system ✓
MDMA supply secured ✓
Psilocybin-supply secured
Therapist training
First patient
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:** 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.

This release has been approved by the Board of Emyria.

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