ASX Announcement

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Ethics approval received for EMD-RX5 Phase 1 Study

Highlights:

- **Emyria has received ethics approval** for its Phase 1 clinical trial of EMD-RX5, a proprietary, highly bioavailable oral formulation of ultra-pure CBD
- The Phase 1 clinical trial of EMD-RX5 will assess the **safety and bioavailability of EMD-RX5 compared to Epidyolex** - the only CBD-only medicine formally registered with the TGA and the FDA
- EMD-RX5 dose form has potential to support **multiple TGA and FDA registration programs,** including an over-the-counter (Schedule 3), CBD treatment for the symptoms of psychological distress
- **Commercial-scale GMP manufacturing** of EMD-RX5 is underway, ensuring sufficient quantity of trial material for all trials required for registration. This includes the current Phase 1 trial and the pivotal Phase 3 trial to follow
- **Site initiation visit completed** at CMAX, in preparation for trial commencement
- **Provisional patent has been filed** for the EMD-RX5 formulation; additional proprietary cannabinoid formulations are currently in development

Emyria Limited (ASX: EMD) (Emyria or the Company), a clinical stage biotechnology company leveraging real-world patient data to develop treatments for unmet needs, is pleased to announce an update on the clinical development program for EMD-RX5.

Emyria has received ethics approval for its Phase 1 clinical trial of EMD-RX5, the Company's first ultra-pure, high-bioavailability cannabidiol (CBD) capsule. The Phase 1 trial is an important first step towards registration and will evaluate the bioavailability of EMD-RX5 as compared to Epidyolex in a crossover design with 12 healthy volunteers.

EMD-RX5 is initially seeking registration as a low-dose, Schedule 3, "over-the-counter" CBD treatment for the symptoms of psychological distress (*previously referred to as the EMD-003 program*).

Recent pharmacokinetic (PK) studies compared the EMD-RX5 capsule to Epidyolex oil. Epidyolex is sold by Jazz Pharmaceuticals (NASDAQ: JAZZ) and is the only registered CBD medicine with both the TGA and FDA. Those studies demonstrated that EMD-RX5 had a higher bioavailability profile compared to Epidyolex. *(See ASX announcement 15 DEC 2021).*

Manufacturing of commercial quantities of GMP-grade EMD-RX5 is currently underway to ensure sufficient quantity of trial material available to cover all pivotal clinical trials (both Phase 1 and Phase 3) as required for the Company's first TGA registration program.

Emyria has successfully completed the site initiation visit for EMD-RX5 at leading Phase 1 clinical trial site, CMAX. Participant recruitment is expected to commence imminently, with dosing of EMD-RX5 to follow.

A provisional patent has been filed to cover Emyria's proprietary formulation of EMD-RX5. Emyria's proprietary Real-World Data (RWD) guided the development of EMD-RX5, which the Company believes has the potential to become a registered treatment for multiple indications. Additional cannabinoid dose forms are currently in planning, also guided and informed by Emyria's growing RWD.

Emyria's Managing Director, Dr. Michael Winlo said: *"Uniquely amongst cannabidiol registration programs, Emyria's Phase 1 clinical trial will directly compare the bioavailability of EMD-RX5's proprietary formulation to the only successfully registered and reimbursed CBD oil in the global market to date, Epidyolex.*

EMD-RX5 is a high-performing and cost-effective CBD capsule with the potential to address multiple indications. Emyria's first registration program is aimed at developing an over-the-counter, Schedule 3 treatment targeting the symptoms of psychological distress. This registration program was developed with insights from Emyria's growing Real-World Data asset.

EMD-RX5 also meets the strict requirements for product purity with both the TGA in Australia and the FDA in the USA, and as such, we believe it has potential to become a registered treatment for multiple clinical indications.

I look forward to providing further updates on EMD-RX5 and our expanding cannabinoid portfolio in the near-term."

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

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About Emyria (www.emyria.com)

Emyria Limited is a data-backed clinical drug development and care delivery company focused on accelerating treatment development and improving patient care.

Emyria's Treatments target unmet needs and are focused on obtaining approval from major global regulators. Emyria's drug development programs are informed by insights generated from extensive analysis of **Emyria Data** - deep, ethically-sourced clinical evidence that is gathered with patients across Emyria's independent clinical services (**Emerald Clinics** - www.emeraldclinics.com.au)

Emyria Data provides deep treatment insights and is therefore a source of unique IP, strategically designed drug development and personalised care programs.

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.
