ASX Announcement

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myriad data.
individual care.

Recruitment commenced for EMD-RX5 Phase 1 Study

Highlights:

- **Participant recruitment, screening and consenting** has commenced for Emyria's Phase 1 clinical trial of EMD-RX5; dosing expected by the end of March 2022
- The Phase 1, 2-way cross-over clinical trial of EMD-RX5 will assess the **safety and bioavailability of EMD-RX5 compared to Epidyolex** in 12 healthy human volunteers who will receive both cannabinoid treatments; Epidyolex is the only CBD-only medicine formally registered with the TGA and the FDA
- EMD-RX5 is a proprietary, highly bioavailable oral formulation of ultra-pure CBD, anticipated to support **multiple TGA and FDA registration programs**
- EMD-RX5 is initially targeting TGA registration as an over-the-counter (Schedule 3), CBD treatment for the symptoms of psychological distress
- The **pivotal Phase 3 study required for registration is expected follow immediately after conclusion of the Phase 1 trial** pending successful ethics approval; since Emyria's extensive and proprietary Real World Data has informed the selection of the target indication, a Phase 2 study is not anticipated to be required

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 participant recruitment, screening and consenting has commenced for the EMD-RX5 clinical development program.

EMD-RX5 is an ultra-pure, highly bioavailable cannabidiol (CBD) capsule with potential to become a registered treatment for multiple indications. EMD-RX5 is the Company's first, proprietary cannabinoid-based medical treatment.

Emyria is initially seeking registration of EMD-RX5 with the TGA as a low-dose, Schedule 3, "over-the-counter" CBD treatment for the symptoms of psychological distress.

Psychological distress is a common mental health problem affecting ~15% of Australian adults [1] with a rising prevalence.Psychological distress is a state of emotional suffering typically characterised by symptoms of depression and anxiety which often coexists with a wide range of chronic conditions [2]. There is currently no over-the-counter treatment for the relief of short-term symptoms of psychological distress.

The full, end-to-end EMD-RX5 development program - encompassing proprietary formulation design, at-scale GMP manufacturing and all clinical trials - has been designed to meet the registration requirements of both the TGA and FDA.

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

The pivotal Phase 3 clinical trial protocol required for registration has already been developed and, pending successful ethics approval, is expected to commence immediately following the Phase 1 trial.

Analysis of Emyria's extensive and proprietary Real World Data has informed the selection of the target indication for EMD-RX5 and therefore a Phase 2 study is not anticipated to be required for registration. Ongoing analysis of Emyria's Real World Data is also informing adjacent indications for EMD-RX5 and additional dose form opportunities for Emyria's expanding drug product pipeline.

Emyria's Managing Director, Dr. Michael Winlo said: *" Emyria's first registration program is aimed at developing an over-the-counter, Schedule 3 treatment targeting the symptoms of psychological distress - a growing global mental health concern affecting about 15% of all adults in Australia alone and which currently has no over-the-counter treatment available.*

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 EMD-RX5 has the potential to become a registered treatment in additional markets and for multiple clinical indications.

Since the EMD-RX5 clinical development program was developed with insights from Emyria's growing Real-World Data asset, the Company is able to move quickly from Phase 1 through to a Pivotal Phase 3 clinical trial.

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.

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

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 clinical stage biotech developing multiple treatments for unmet needs powered by real-world patient data. Emyria's model is aimed at 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.