ASX Announcement

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Emyria launches second highly bioavailable, ultra-pure CBD capsule, EMD-RX7

Highlights:

- EMD-RX7 is Emyria's second 100% owned, ultra-pure CBD dose form and follows the development of EMD-RX5, now in Phase 1 clinical trials
- **EMD-RX7** demonstrates more than 4 times the bioavailability (a measure of the amount of the drug reaching the bloodstream) compared to the only registered CBD oil - Epidyolex - in a recent pharmacokinetic animal study *(see Figure 1)* meaning lower doses may be required for clinical results
- EMD-RX7 will target indications responsive to higher CBD exposures as guided by Emyria's extensive Real World Data gathered with 6,000 patients
- Emyria is now advancing two proprietary, ultra-pure CBD treatments towards registration with the Therapeutic Goods Administration (TGA) in Australia and the Food and Drug Administration (FDA) in the USA *(see Table 1)* :
  - **EMD-RX5** targeting a 1 to 3 capsules per day, "over-the-counter" scheduling for a range of low-dose, CBD-only indications including psychological distress and;
  - **EMD-RX7** targeting a 1 to 3 capsules per day prescription-only scheduling for a range of indications requiring higher CBD dosing
- High-dose CBD (>300mg/day) has shown clinical efficacy and promise in several clinical indications (eg Epilepsy [1], Rheumatoid arthritis [2], Social Anxiety Disorder and Insomnia [3], and Graft versus host disease [4])
- EMD-RX5 program advancing; Phase 1 clinical trials underway
- EMD-RX7 Phase 1 trial in planning and is expected to commence in H2, 2022
- Additional proprietary cannabinoid formulation development is planned to further expand Emyria's cannabinoid-based medical treatment (CBMT) portfolio
- Emyria's growing clinical development programs encompass proprietary cannabinoid treatments and novel MDMA-analogues

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 the launch of its second proprietary, ultra-pure CBD formulation - EMD-RX7.

In a preclinical pharmacokinetic study, EMD-RX7 was shown to have more than 4 times the bioavailability compared to an equivalent dose of Epidiolex. *(see Figure 1)*

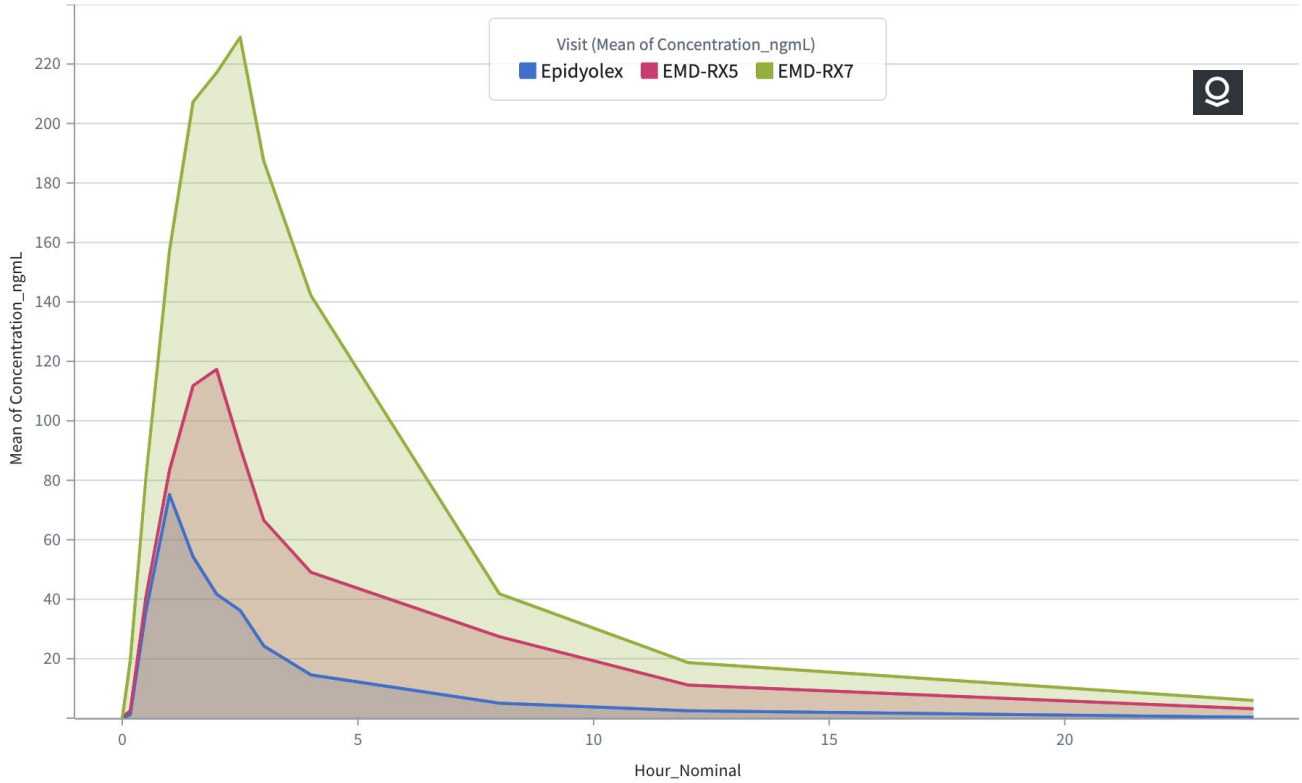

Fig 1. Mean concentration (ng/ml) of CBD : Epidyolex vs EMD-RX5 and EMD-RX7 over 24 hours
(A comparison of EMD-RX5 to Epidyolex was shared in ASX announcement dated 15 DEC 2021)

Bioavailability is a measure of the amount of drug that is fully available in the bloodstream. A drug with a high relative bioavailability may require lower doses to achieve clinical benefits.

CBD is known to have poor bioavailability. For Epidyolex oil, in the fasted state, only 6.49% of consumed CBD enters the bloodstream [5]. This means that, on average, for every 100mg of CBD oil consumed, only 6.49mg reaches the bloodstream. For indications requiring high CBD doses, large quantities of oil must be consumed to achieve a clinical outcome. In Australia, where most treatments are unregistered and unreimbursed, higher CBD dosing needs can be cost prohibitive to patients.

Highly bioavailable treatments, like EMD-RX5 and EMD-RX7, allow for smaller, more convenient, oral dosing regimes for patients and lower ingredient costs since more of the active ingredient can be absorbed without having to take higher doses.

Emyria has been developing a novel and proprietary CBD capsules with Altasciences (*See ASX announcement 27 August 2021*). The program has yielded two promising dose forms with bioavailability advantages compared to the only registered CBD medicine.

Epidyolex is the world's only plant-derived, CBD-only medicine registered with both the FDA and TGA for the treatment of a rare type of epilepsy. Epidyolex is also the only CBD medicine subsidised by Australia's Pharmaceutical Benefits Scheme (PBS) [X]. Epidyolex is sold by Jazz Pharmaceuticals (NASDAQ: JAZZ) and is the only registered CBD medicine with both the TGA and FDA.

Emyria's growing proprietary cannabinoid-based medical treatment (CBMT) portfolio now comprises two distinct, proprietary capsules that support convenient oral dosing regimes but for different indication targets *(see Table 1)*. EMD-RX5 is formulated to target low-dose (<150mg/day CBD), "over-the-counter" indications. The more bioavailable EMD-RX7 may allow for similarly convenient, once to twice daily, oral dosing for indications requiring higher daily CBD exposures.

Emyria's proprietary Real World Data (RWD) is now guiding the selection of suitable clinical indications for EMD-RX7 which will be announced as the Phase 1 clinical trial commences in H2, 2022.

Table 1: Emyria's current CBD dose forms portfolio

	Emyria portfolio	
Feature	**EMD-RX5**	**EMD-RX7**
Active pharmaceutical ingredient	Ultra-pure CBD	Ultra-pure CBD
Dose form	Oral capsule	Oral capsule
Bioavailability advantage over equivalent Epidyolex dosing in animal models	> 2 times greater	> 4 times greater
Ownership	100% Emyria owned	100% Emyria owned
Scheduling focus	Over-the-counter, low-dose (<150mg / day CBD)	Prescription scheduling, high-dose (>150mg /day CBD)
Convenient dosing regime	1-3 small capsules per day	1-3 small capsules per day
Target clinical indications	*Multiple*: Starting with: - psychological distress - irritable bowel syndrome - others in planning	*Multiple*: to be announced following completion of Phase 1 clinical trial
Clinical development stage	Phase 1: active Phase 2: *not required due to Real World Data* Phase 3: Expected to commence May 2022	Phase 1: Expected to commence H2, 2022

Emyria's Managing Director, Dr. Michael Winlo said: *"Following the commencement of our Phase 1 clinical trial for EMD-RX5, we are delighted to announce the expansion of our proprietary, ultra-pure, CBD treatment portfolio with the addition of EMD-RX7.*

Emyria's Real World Data suggests there are a range of clinical indications that respond to high daily CBD doses. However, as all CBD treatments in Australia are currently unregistered (with the exception of Epidyolex), patients must pay significant out-of-pocket costs to receive cannabinoid treatments.

We also know that most CBD available to patients has poor bioavailability, meaning only a small amount of active medicine enters the bloodstream where it can be effective. This is why we have developed a range of convenient, ultra-pure CBD capsules with improved bioavailability.

EMD-RX5 is an ideal dose form to support our low-dose registration strategy. Now, with EMD-RX7, we have a convenient dose form that we believe can deliver higher CBD exposures more efficiently allowing us to target a range of prescription-only indications - in other words, help the broad range of major unmet needs that affect the patients we treat every day at our clinical service subsidiary, Emerald Clinics.

We are now planning our Phase 1 trial for EMD-RX7 and will continue to develop unique, proprietary, ultra-pure, cannabinoid-based medical treatments for other indications."

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

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REFERENCES:

[1] Billakota S, Devinsky O, Marsh E. Cannabinoid therapy in epilepsy. Current opinion in neurology. 2019 Apr 1;32(2):220-6.
[2] Lowin T, Tingting R, Zurmahr J, Classen T, Schneider M, Pongratz G. Cannabidiol (CBD): A killer for inflammatory rheumatoid arthritis synovial fibroblasts. Cell death & disease. 2020 Sep 1;11(8):1-1.
[3] Zhornitsky S, Potvin S. Cannabidiol in humans—the quest for therapeutic targets. Pharmaceuticals. 2012 May;5(5):529-52.
[4] Yeshurun M, Shpilberg O, Herscovici C, Shargian L, Dreyer J, Peck A, Israeli M, Levy-Assaraf M, Gruenewald T, Mechoulam R, Raanani P. Cannabidiol for the prevention of graft-versus-host-disease after allogeneic hematopoietic cell transplantation: results of a phase II study. Biology of Blood and Marrow Transplantation. 2015 Oct 1;21(10):1770-5.
[5] https://www.tga.gov.au/sites/default/files/auspar-cannabidiol-210115.pdf

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.