ASX Announcement

25 May 2022

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EMD-RX5 demonstrates excellent safety and bioavailability in Phase 1 study

Highlights:

- EMD-RX5 - Emyria's proprietary ultra-pure CBD capsule - demonstrates excellent bioavailability and dose delivery profile for targeted indications

- Phase 1 pharmacokinetic (PK) crossover study with Epidyolex®, the only TGA and FDA registered CBD medicine, shows EMD-RX5 delivers:
  - **excellent safety and tolerability** with no gastrointestinal upset or adverse events of concern at test dose of 150mg
  - **equivalent bioavailability** and **less 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
  - ***twice the bioavailability*** compared to other, plant-derived CBD products with published pharmacokinetics data *(see Figure 1)*

- EMD-RX5 Phase 1 results expand Emyria's program to register multiple breakthrough solid dosage forms of ultra-pure CBD with the TGA and FDA

- Emyria's S3 TGA registration program for EMD-RX5 now advancing to pivotal Phase 3 clinical trials following planned receipt of ethics approval

Emyria Limited (ASX: EMD) (Emyria or the Company), a clinical stage biotech developing treatments for unmet needs powered by real-world patient data, is pleased to report positive Phase 1 trial data for EMD-RX5 indicating ideal bioavailability, safety and tolerability among 12 healthy and demographically diverse volunteer subjects.

Emyria's Managing Director, Dr. Michael Winlo said: *"These pharmacokinetic data show Emyria has rapidly developed a unique, ultra-pure cannabidiol capsule with excellent safety and tolerability and highly favourable drug delivery and absorption characteristics.*

Compared to Epidyolex, the sole CBD-only medicine registered with the TGA and FDA, EMD-RX5 provides equivalent total drug exposures over 24 hours with a more predictable and sustained drug release.

These results confirm EMD-RX5's suitability as a multi-indication treatment of chronic conditions and support Emyria's initial over-the-counter drug registration program targeting the symptoms of psychological distress.

EMD-RX5 was also shown to provide more than twice the bioavailability of other, plant-derived CBD products in Australia with published pharmacokinetic data, helping further differentiate Emyria's growing ultra-pure cannabinoid drug development and global registration programs."

Clinical advantages of Emyria's ultra-pure CBD revealed in Phase 1 trial

EMD-RX5's proprietary capsule formulation demonstrated excellent safety and tolerability with no notable adverse events or gastrointestinal upset.

EMD-RX5 was bioequivalent to Epidyolex® in total drug exposure (bioavailability) providing potential for Emyria to leverage prior data on Epidyolex® to support drug development and registration efforts in the USA.

EMD-RX5 is estimated to have more than twice the bioavailability of other Australian CBD products with published pharmacokinetic data. *(see Figure 1)*

EMD-RX5 also showed:

- **lower drug concentration variability between participants** meaning EMD-RX5 has more predictable dosing characteristics (fewer "highs" and "lows")
- **higher CBD exposures 3 and 8 hours post dosing** meaning CBD levels are sustained for longer providing an ideal dosing profile for Emyria's initial target clinical indications and supporting once to twice daily dosing.

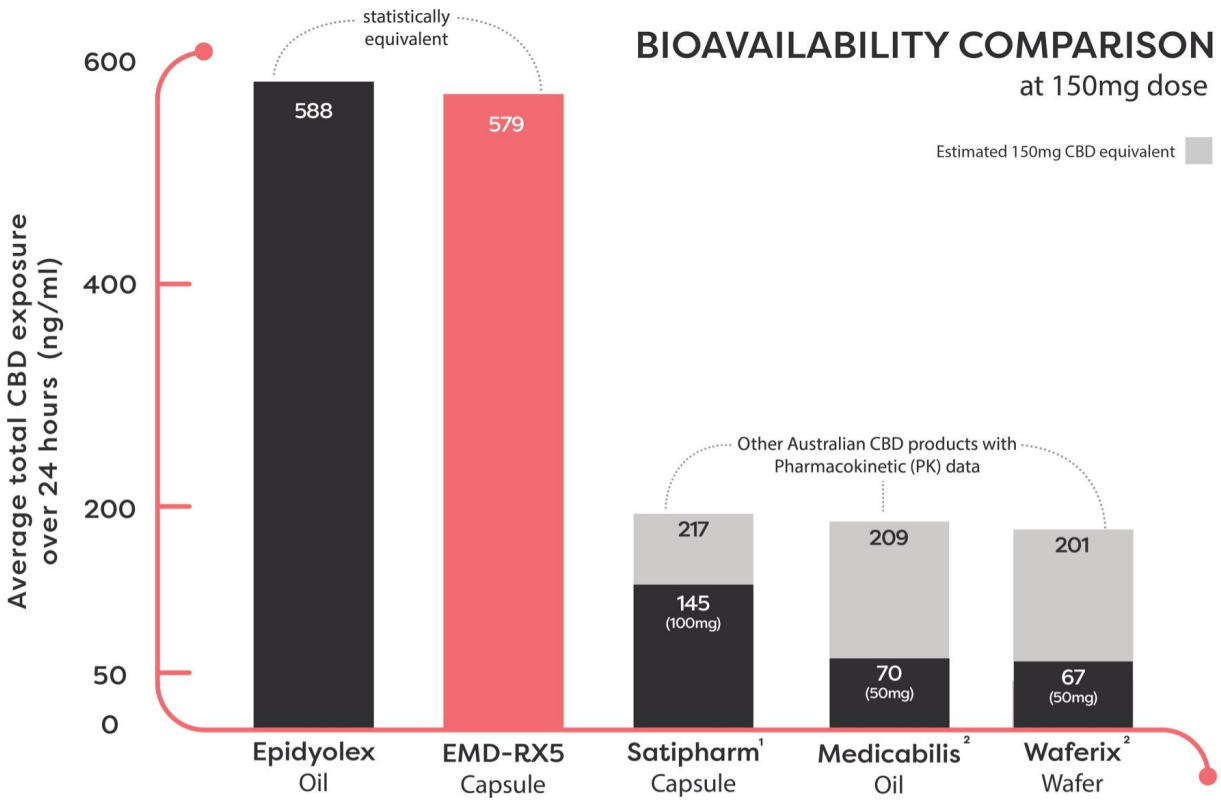

Figure 1: A comparison of total CBD exposures delivered over 24 hours by different CBD products

Next steps and additional drug development progress

EMD-RX5 will now advance to pivotal Phase 3 clinical trials to support the TGA registration of EMD-RX5 as an over-the-counter (OTC) treatment for the symptoms of psychological distress. *(See ASX release 12 April 2022)*

Psychological distress affects 15% of the adult population but has no OTC treatment available. [3]

EMD-RX7, targeting prescription-only high dose CBD indications, begins production for Phase 1 trials next quarter and further proprietary ultra-pure cannabinoid-based dose forms are in planning guided by the Australian Emyria Clinical e-Registry **(AECeR**) co-created with patients cared for at its subsidiary - Emerald Clinics. *(See ASX release 17 March 2022)*

The Company continues to advance planning to pursue FDA registration targets in addition to exploring partnerships that can accelerate benefits to patients and create shareholder value.

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

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[2] Hosseini A, McLachlan AJ, Lickliter JD. A phase I trial of the safety, tolerability and pharmacokinetics of cannabidiol administered as single-dose oil solution and single and multiple doses of a sublingual wafer in healthy volunteers. Br J Clin Pharmacol. 2021 Apr;87(4):2070-2077. doi: 10.1111/bcp.14617. Epub 2020 Nov 18. PMID: 33075170.

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

Appendix

Key study information:

Study design, product and participant details:
A randomised open label, two way crossover study comparing the Pharmacokinetic (PK) characteristics of one 150mg dose of EMD-RX5 Cannabidiol (CBD) capsules with one 150mg dose of Epidyolex CBD oil (100mg/mL) in 12 healthy male and female volunteers aged 18-65.

Each participant received a single dose of EMD-RX5 or Epidyolex followed by a 1 week washout before receiving the alternative dose form.

Study conducted according to ICH-GCP guidelines.

Investigational product prepared according to Good Manufacturing Practice (GMP) standards.

Primary endpoint:
Describe the pharmacokinetic parameters of EMD-RX5 CBD 50mg capsules after a once daily administration of 150mg. Measurements to include plasma CBD PK parameters Cmax; Tmax; AUC0-24hr; AUCinf; T1/2 at the following times: pre-dose, 30 mins, 1 hour, 2 hours, 3 hours, 4 hours, 5 hours, 6 hours, 8 hours, 12 hours and 24 hours post dose.

Site details:
CMAX Clinical Research, Adelaide.

Principal Investigator:
Dr. Jonathan Newchurch

ANZCTR entry:
ACTRN12622000427774

Figure 2: [A] EMD-RX5 "ultra-pure CBD" capsules and [B] Epidyolex CBD oil

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DRUG DEVELOPMENT **PIPELINE**

PLANNING PHASE · ACTIVE MODE · FAST TRACKED WITH REAL WORLD DATA · COMPLETE

ULTRA-PURE **CANNABINOID MEDICINES**

EMYRIA'S ULTRA-PURE CANNABINOID TREATMENTS have been uniquely formulated to:

- Meet FDA requirements for registered medicines
- Have improved bioavailability
- Meet patient preferences for a solid, oral dose form

Proprietary **REAL WORLD DATA** supports **EMYRIA'S ACCELERATED REGISTRATION PROGRAMS,** carefully gathered with over **6,000 patients** *(and growing)* receiving personalised cannabinoid treatment across Emyria's clinical service subsidiary.

CLINICAL PROGRAMS

	PRE-CLINICAL DOSE DEV.	CLINICAL DEV. PROGRAM PHASES P1	P2	P3	REGISTRATION PROGRESS AUSTRALIA TGA	USA FDA
EMD-RX5 Over-the-counter treatment for symptoms of psychological distress	✓	✓	✓ FT RWD		PLANNING	
EMD-RX5 Over-the-counter treatment for symptoms of IBS	✓	✓	✓ FT RWD		PLANNING	
EMD-RX7 ULTRA-PURE, prescription CBD treatment for Multiple Medical Conditions *	✓	PLANNING				
Other **ULTRA PURE** HIGH BIOAVAILABILITY CBD FORMULATIONS ***in development*** targeting unmet needs	PLANNING					

* *To be determined*

NEXT-GEN **MDMA LIKE MEDICINE**

Emyria is developing a **one-of-a-kind**, proprietary library of **OVER 100 UNIQUE COMPOUNDS** *(& growing)* Inspired by -3. 4 -Methylenedioxymethamphetamine *(also known as "MDMA" or "ecstasy")* and developed over ten years by Dr. Matt Piggott and his team at the University of Western Australia.

ADVANCED CLINICAL & IP DEVELOPMENT STRATEGY focussed on identifying novel small molecules with potential to become registered treatments as:

- Next-generation psychedelic-assisted therapies
- Novel neurological therapies
- Novel non-neurological therapies

THERAPEUTIC FOCUS AREA

	PRE-CLINICAL DEV. NEW COMPOUND	ADVANCE SCREENING	CLINICAL DEV. PROGRAM PHASES PRE-CLIN. TRIALS	LEAD SELECTION	CLIN. TRIALS	REGISTRATION PROGRESS AUSTRALIA TGA	USA FDA
NEXT-GEN MDMA Targeting PTSD psychedelic-assisted therapies for neurological *(Parkinson's)* and non - neurological disorders	A	A	PLANNING				

About Emyria (www.emyria.com)

Emyria Limited develops biopharmaceuticals guided by proprietary Real-World Data collected with patients across its wholly-owned clinical service subsidiary, Emerald Clinics.

Emyria's current clinical development programs are focussed on the registration of proprietary formulations of cannabinoid-based medical treatments (CBMTs) and novel MDMA ('ecstasy') analogues with major global regulators. Emyria's programs target major unmet needs such as mental health disorders and chronic pain.

Emyria's Real World Data (RWD) guides each of Emyria's clinical development programs and care models. Emyria RWD is deep, ethically-sourced clinical evidence gathered with thousands of patients who also receive personalised care at Emerald Clinics.

Emyria is therefore uniquely providing care to patients, generating clinical evidence and advancing multiple proprietary treatment programs towards registration.

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.