ASX Announcement

14 Apr 2022

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EMD-RX5 Dosing to Complete for Phase 1 Clinical Trial

Highlights:

- Dosing of Emyria's ultra-pure CBD capsule, EMD-RX5, is expected to complete today for 12 trial participants at CMAX in Adelaide
- The Phase 1 clinical trial is assessing the safety, tolerability and bioavailability of EMD-RX5 compared to Epidyolex - the sole CBD-only medicine registered with the TGA and the FDA - and will support Emyria's registration submission to the TGA
- EMD-RX5 is initially targeting registration as an over-the-counter (Schedule 3) treatment for the symptoms of psychological distress which affects 15% of the adult population and for which there is currently no over-the-counter treatment [1]

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 that participant dosing of EMD-RX5 is complete. A final data report is due next month.

EMD-RX5 is Emyria's first, wholly-owned, proprietary formulation of ultra-pure cannabidiol (CBD). Recent preclinical pharmacokinetic (PK) studies comparing EMD-RX5 capsule to Epidyolex oil demonstrated that EMD-RX5 had higher bioavailability compared to Epidyolex. *(See ASX release 17 Mar 2022)*

This Phase 1 clinical trial is assessing the safety, tolerability and bioavailability of EMD-RX5 capsules compared to Epidyolex oil in 12 healthy human volunteers *(full details below)*. Epidyolex is sold by Jazz Pharmaceuticals (NASDAQ: JAZZ) and is the sole CBD medicine registered with both the TGA and FDA. *(See ASX release 15 DEC 2021)*

Emyria's EMD-RX5 capsules were uniquely developed to:

- Meet FDA requirements for ingredient purity by using ultra-pure CBD
- Improve the bioavailability of CBD
- Create a palatable dose form for patients

As a result, Emyria believes EMD-RX5 has the potential to address multiple clinical indications as a registered medicine where low doses of CBD appear to be effective.

Emyria is initially targeting the registration of EMD-RX5 with Australia's Therapeutic Goods Administration (TGA) as an over-the-counter (Schedule 3) treatment for the symptoms of psychological distress before commencing other registration programs with the same dose form.

The symptoms of psychological distress can present as sleep disturbance, gastrointestinal upset and mild anxiety. These symptoms are estimated to affect about 15% of the adult population with a higher prevalence in patients with chronic disease. [1] There is currently no over-the-counter treatment available for the symptoms of psychological distress.

A pivotal Phase 3 clinical trial to support the registration of EMD-RX5 has been planned and is expected to commence immediately following the successful completion of the Phase 1 study. Leading Contract Research Organisation (CRO) and Site Management Organisation (SMO), Clinitrials, have recently been appointed to manage the Pivotal Phase 3 across 5-6 sites in Australia. *(See ASX release 13 APR 2022)*

Emyria's wholly-owned clinical service subsidiary, already operating across Australia, is expected to further accelerate recruitment by helping identify suitable patients who will be referred for formal screening at independent sites managed by Clinitrials.

Emyria has developed a second, ultra-pure CBD medicine with potentially higher bioavailability, EMD-RX7 which is now also progressing towards a Phase clinical trial. Further cannabinoid-based medical treatments are in development. *(See ASX release 17 Mar 2022)*

Emyria's deepening drug development pipeline also includes new chemical entity development with MDMA-analogues. *(See ASX release 08 Dec 2021)*

Emyria's Managing Director, Dr. Michael Winlo said: *"Now dosing of EMD-RX5 has completed we can commence the data analysis to compare the safety, tolerability and bioavailability of EMD-RX5 to the only sole registered and reimbursed CBD oil in the global market to date, Epidyolex and move directly to our pivotal Phase III clinical trial with partner Clinitrials.*

Our proprietary Real World Data, gathered with thousands of patients, is helping guide each of our drug development and registration activities which also includes EMD-RX7 targeting indications requiring higher CBD exposures.

I look forward to providing further updates on our registration progress as well as our growing cannabinoid and MDMA analogue pipeline in the near-term."

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

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References:

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

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

Total study expected to last 2 weeks with an additional 1 week follow-up following last dose received.

Study to be conducted according to ICH-GCP guidelines.

Investigational product has been prepared according to Good Manufacturing Practice (GMP) standards and made by Altasciences, Philadelphia.

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

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Emyria's clinical development pipeline:

Ultra-pure Cannabinoid Medicines

Complete | Active | In Planning

Emyria's cannabinoid-based medical treatments (CBMTs) have been developed with world-leading experts to meet FDA requirements and directly address the major challenges of of current cannabinoid therapy. Emyria's CBMTs are ultra-pure, highly bioavailable, convenient and cost-effective.

Our CBMT development and registration programs are guided by insights from real world patients. Emyria's unique, proprietary Real World Data (RWD) accelerates the entire end-to-end development process and helps ensure our CBMTs have the potential to become registered medicines for multiple, major unmet clinical needs.

	Pre-Clinical Development	Clinical Development Program			Registration Progress	
Clinical Program	Proprietary Dose Form Development	Phase 1	Phase 2	Phase 3	Australia (TGA)	USA (FDA)
EMD-RX5 psychological distress low-dose, high bioavailability CBD	Accelerated via RWD	Active	Accelerated via RWD	Expected start date June 2022	In planning	
EMD-RX5 irritable bowel syndrome low-dose, high bioavailability CBD	Accelerated via RWD	Active	Accelerated via RWD			
EMD-RX7 multiple potential indications higher dose, highly bioavailable CBD	Accelerated via RWD	In planning		In planning		
Additional novel dose forms	In planning					

Next-generation MDMA analogues

Emyria has exclusive access to a world-class, growing MDMA analogue library that already contains over 100 unique compounds. The original library was developed over 10 years by Dr. Matt Piggott at the University of Western Australia. Each MDMA analogue is structurally similar to -3.4 -Methylenedioxymethamphetamine (MDMA, 'ecstasy') but with unique properties that make them attractive small molecules to develop into proprietary registered treatments.

Recent research has revealed that MDMA, when given alongside psychotherapy, can be a beneficial treatment for a range of major mental health disorders like Post-Traumatic Stress Disorder (PTSD). Emyria is leading a major opportunity to develop the next generation of psychedelic-assisted therapies as well as treatments for other neurological and non-neurological disorders.

	Pre-Clinical Development Progress		Clinical Development Progress			Registration submission	
Therapeutic Focus Area	New Compound Creation	Advanced Screening	Pre-Clinical	Lead Selection	Clinical Trials	Australia (TGA)	USA (FDA)
Next-generation MDMA - psychedelic-assisted therapies - neurological disorders (Parkinson's) - non-neurological disorders	Active	Active	Animal models in 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.