ASX Announcement

07 Apr 2022

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Dosing Commences for EMD-RX5 Phase 1 Human Clinical Trial

Highlights:

- **Participant dosing has commenced** at CMAX for Emyria's Phase 1 clinical trial of EMD-RX5, a proprietary capsule of highly bioavailable ultra-pure CBD
- The Phase 1 clinical trial will assess the **safety and bioavailability** of EMD-RX5 **compared to Epidyolex** - the sole CBD-only medicine formally registered with the TGA and the FDA; *full study information provided below*
- EMD-RX5 showed **greater peak concentration and improved bioavailability** compared to the equivalent dose of Epidyolex over a 24 hour period in a recent pharmacokinetic animal study *(See ASX release 17 MAR 2022)*
- EMD-RX5 is currently **targeting registration** as an over-the-counter (Schedule 3), CBD treatment for the symptoms of psychological distress which affects 15% of the adult population and for which there is no over-the-counter treatment [1]
- **Pivotal Phase III trial** design and planning completed, expected to commence immediately following the successful completion of the Phase 1 study
- EMD-RX5 is the first of two unique, 100% owned, solid oral CBD dose forms developed by Emyria using ultra-pure, nature-identical, CBD with the potential to support multiple TGA and FDA indications
- Registration programs are guided by **Emyria's growing proprietary Real-World Data (RWD),** which currently consists of cannabinoid dose response insights on more than 6,000 patients

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 has commenced for a Phase 1 trial comparing EMD-RX5 with Epidyolex.

EMD-RX5 is Emyria's first solid, oral dose form of ultra-pure CBD. Recent pharmacokinetic (PK) studies comparing EMD-RX5 to Epidyolex oil demonstrated that EMD-RX5 had higher bioavailability compared to Epidyolex. Epidyolex is sold by Jazz Pharmaceuticals (NASDAQ: JAZZ) and is the only registered CBD medicine with both the TGA and FDA. *(See ASX release 15 DEC 2021).*

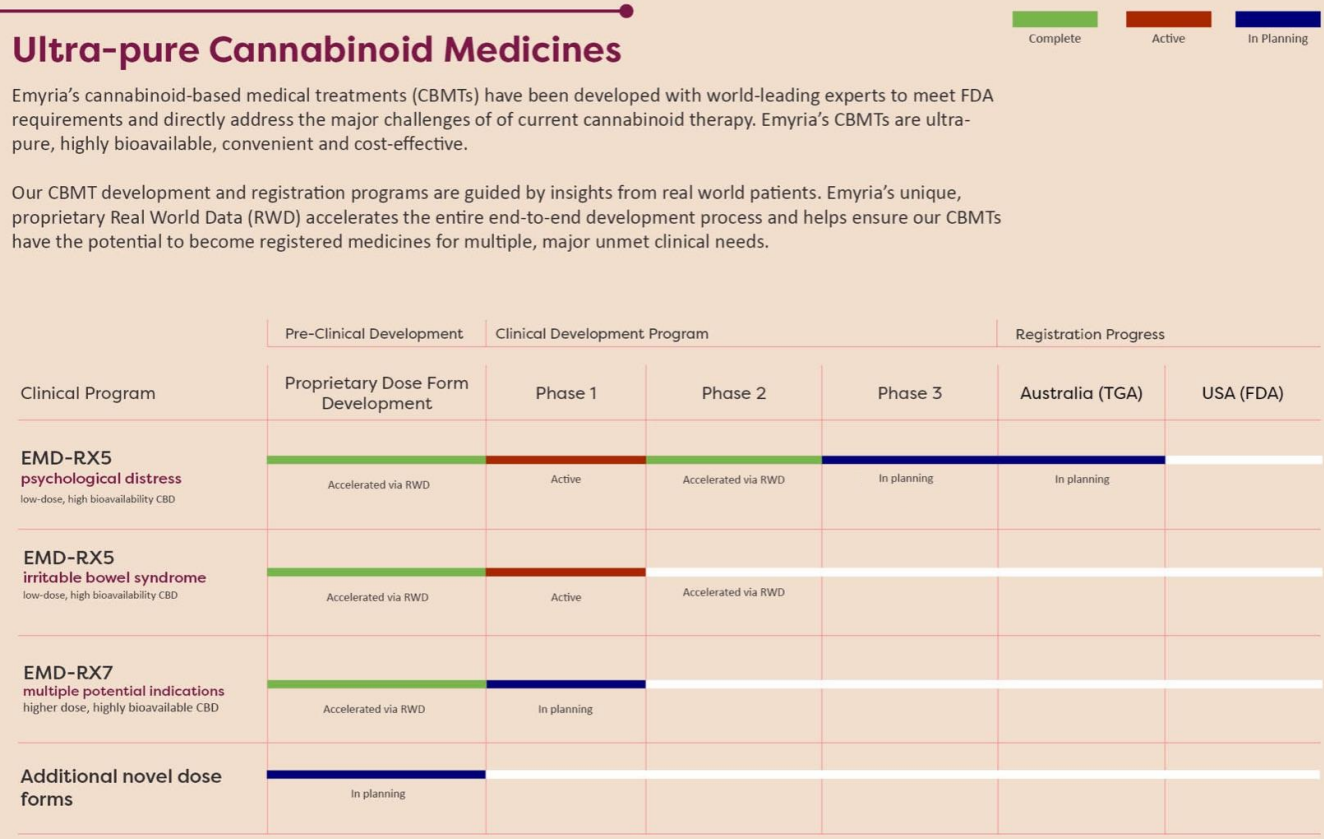
EMD-RX5 is Emyria's first ultra-pure CBD biopharmaceutical with the potential to address multiple clinical indications. EMD-RX5 is initially seeking registration as a low-dose, Schedule 3, "over-the-counter" CBD treatment for the symptoms of psychological distress, a condition affecting nearly 15% of adults and with no approved over-the-counter treatment. [1]

Emyria's clinical development pipeline:

Ultra-pure Cannabinoid Medicines

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.



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.

A pivotal, Phase 3 clinical trial has been developed and expected to run across multiple independent clinical sites across Australia. Emyria's wholly-owned clinical service subsidiary, already operating across Australia, is expected to assist in accelerating recruitment by helping identify suitable patients who will then be referred for formal screening at the independent sites.

Phase 1 clinical trials are also in planning for EMD-RX7, Emyria's second, ultra-pure CBD dose form targeting prescription indications where higher CBD exposures are required. *(See ASX release 17 MAR 2022).*

Emyria's proprietary Real-World Data (RWD) - covering outcomes data on over 6,000 patients receiving care at Emyria's clinical service subsidiary - has guided the development of Emyria's growing portfolio of ultra-pure cannabinoid biopharmaceuticals.

Emyria's Managing Director, Dr. Michael Winlo said: *"Our Phase 1 clinical trial, now commenced, will directly compare the safety and bioavailability of EMD-RX5 to Epidyolex. Our first ultra-pure cannabidiol formulation versus the only successfully registered and reimbursed CBD oil in the global market to date.*

The head-to-head comparison with the global leader in registered cannabinoid medicines - Epidyolex - is important to us, as Emyria is fully committed to developing differentiated registered biopharmaceuticals in large global markets for major clinical indications.

Planning for the upcoming Pivotal Phase III clinical trials for EMD-RX5 has been completed, and is expected to commence immediately after the completion of this Phase 1 study. Additional Phase 1 trials are also planned for our other ultra-pure cannabinoid medicines including EMD-RX7, which is 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.

For further information:

Dr. Michael Winlo
Managing Director
+61 (0) 8 6559 2800
mwinlo@emyria.com

Lexi O'Halloran
Media/Investor Relations
+61 (0) 404 577 076
investors@emyria.com

Andrew Williams
Media Relations
+61 (0) 412 614 125
awilliams@emyria.com

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

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.