ASX Announcement

15 Dec 2021

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individual care.

Positive animal study data received for Emyria's novel, ultra-pure CBD capsule (EMD-003)

Highlights:

- Emyria has received positive preliminary results from a pre-clinical head-to-head animal study comparison of Emyria's proprietary, ultra-pure cannabidiol (CBD) formulation (**EMD-003 *capsule***) to the only registered CBD product in Australia and the US (**Epidyolex *oil***)
- EMD-003 had a greater peak concentration and improved bioavailability compared to an equivalent dose of Epidyolex over a 24 hour period (*see Figure 1*)
- EMD-003 is comprised of ultra-pure CBD and FDA-approved ingredients, simplifying future registration with major regulators like the Therapeutic Goods Administration (TGA) in Australia and the Food and Drug Administration (FDA) in the USA
- Emyria is targeting a Schedule 3 registration with the TGA for EMD-003 in 2022
- Pivotal clinical trials due to commence Q1, 2022 starting with a Phase 1, healthy volunteer trial of EMD-003 which will also use Epidyolex as a comparator

Emyria Limited (ASX: EMD) (Emyria or the Company), a data-backed drug development and care delivery company, is pleased to announce positive bioanalytical results of its proprietary, ultra-pure CBD formulation.

Emyria has been developing a proprietary CBD capsule with Altasciences. [1]

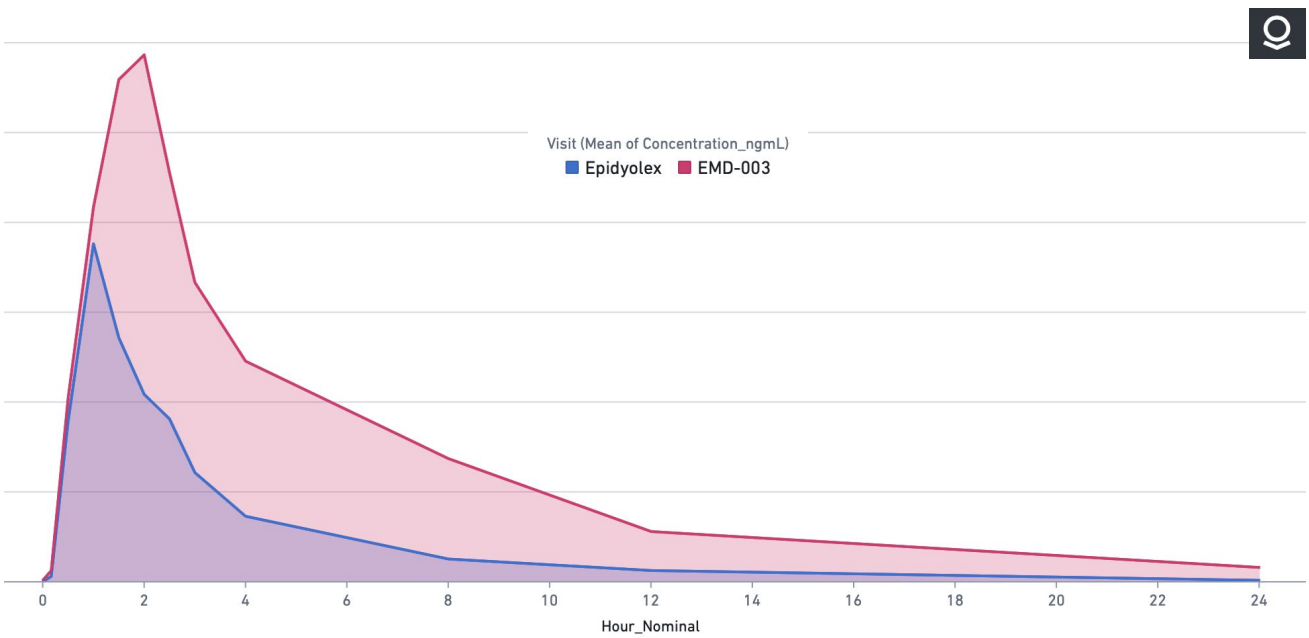

Fig 1. Mean concentration (ng/ml) of CBD : Epidyolex vs EMD-003 over 24 hours

In a comparative animal model, EMD-003 showed higher peak blood concentrations and greater bioavailability compared to Epidyolex over 24 hours.

Bioavailability is a measure of the amount of drug that is fully available in the bloodstream. A drug with a high bioavailability may mean that a lower dose can be administered to a patient in order to achieve a clinical benefit compared to a drug with a lower bioavailability.

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) [2].

Emyria's EMD-003 dose form is targeting registration as a low-dose, over-the-counter CBD medicine with the TGA in 2022.

Emyria's Managing Director, Dr. Michael Winlo said: *"We're delighted to receive positive bioanalysis results for Emyria's proprietary formulation of an ultra-pure CBD capsule.*

We were eager to evaluate the bioavailability of our formulation compared to the only successfully registered and reimbursed CBD oil in the market to date, Epidyolex.

These animal study results suggest Emyria has developed a novel, high performing and cost-effective CBD capsule that can meet the strict registration requirements for product quality and purity with both the TGA in Australia and the FDA in the USA.

We are now advancing our EMD-003 registration program, which is supported by Emyria's proprietary real-world evidence, collected with thousands of patients.

These results also give us the confidence to launch additional cannabinoid registration programs with the TGA and FDA based on the underlying formulation approach, and we look forward to providing more updates on EMD-003 and additional registration programs in the near-term."

Preclinical pharmacokinetic (PK) study design

Comparison of EMD-003 and Epidyolex was performed by Calvert Labs an Altasciences company using an 8 canine subject, cross-over animal trial design. Each of the 8 subjects were administered equivalent single doses of EMD-003, Epidyolex and two other test formulations. There was a one week wash-out in between dosing (a period of no further drug administration). For each treatment, 12 blood samples were collected over 24 hours for each subject and analysed for CBD concentration.

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

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References:

[1] ASX Announcement 27 August 2021
[2]https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/historic-pbs-listing-for-australians-with-a-rare-epilepsy-condition

About Emyria (www.emyria.com)

Emyria Limited is a data-backed clinical drug development and care delivery company focused on 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.