ASX Announcement

20 Jan 2022

emyria
myriad data.
individual care.

Phase 1 trial to commence Q1, 2022 for Emyria's ultra-pure CBD capsule; GMP production underway; Activities support EMD-003 program

Highlights:

- **Emyria to commence Phase 1 human clinical trials** to assess the safety and bioavailability of its first ultra-pure CBD formulation as compared to Epidyolex - the only TGA- and FDA-registered CBD medicine

- Emyria's proprietary formulation, named **'EMD-RX5'**, expected to support multiple Real-World Evidence (RWE) guided registration programs for Emyria including:
  - An over-the-counter, low-dose CBD treatment for the temporary symptoms of psychological distress **(the 'EMD-003' program)** and;
  - A CBD treatment for the relief of symptoms associated with Irritable Bowel Syndrome (IBS) **(the 'EMD-004' program)**

- **GMP-grade production** of EMD-RX5 has also commenced to support the pivotal randomised clinical trials required for TGA submission of EMD-RX5 as a Schedule 3, over-the-counter medicine for psychological distress (EMD-003)

- **Phase 1 trial protocol has been submitted to ethics** with recruitment expected to start in Q1, 2022.

- Leading Phase 1 facility, CMAX has been selected to conduct the study

- Pivotal Phase 3 trial expected to commence after completion of the Phase 1 trial; Phase 3 study protocol developed, and site network engaged

- Further registration programs utilising EMD-RX5 are in development

Emyria Limited (ASX: EMD) (Emyria or the Company), a data-backed drug development and care delivery company, is pleased to announce that Phase 1 clinical trials are to commence for its leading ultra-pure CBD drug candidate, referred to as **EMD-RX5**.

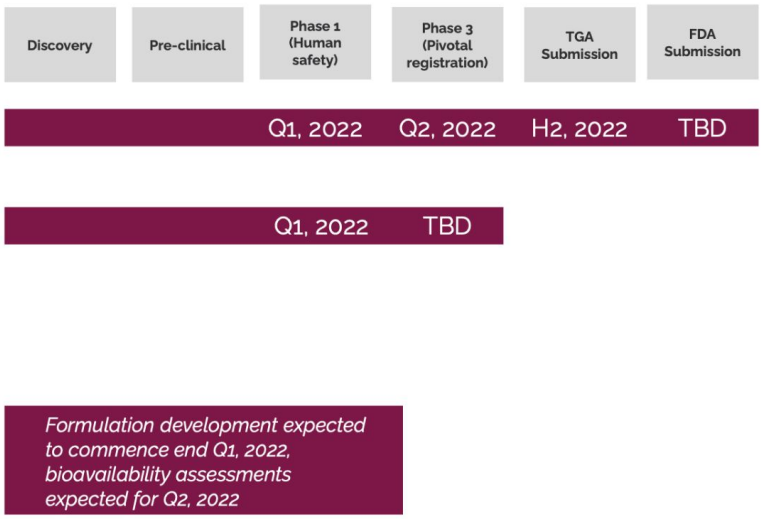
EMD-RX5 is a proprietary, highly bioavailable oral CBD formulation developed to meet the strict product purity requirements of both the TGA in Australia and the FDA in the USA. EMD-RX5 is expected to be a candidate treatment for multiple clinical indications.

Pure CBD is structurally and biochemically identical to plant-derived CBD [1] and also:

- tasteless and odourless
- highly stable at room temperature and;
- free from the impurities associated with plant-derived CBD (such as heavy metals, pesticide residues and multiple other cannabinoids including undetectable levels of THC). [2]

Emyria's cannabinoid development pipeline:

Proprietary drug formulation	Drug development & registration program	Target indication	Current Status
EMD-RX5	**EMD-003**	Symptoms of psychological distress	Phase 1, Q1, '22
EMD-RX5	**EMD-004**	Symptoms of Irritable Bowel Syndrome (IBS)	*Phase 1, Q1 2022,*
In development - additional cannabinoid formulations	*EMD-00X*	*In development - guided by dose-response insights from Emyria RWE*	*In development*



The Phase 1 clinical trial of EMD-RX5 will be conducted at CMAX Clinical Research (CMAX) following ethics approval and will assess the safety and bioavailability of EMD-RX5 compared to Epidyolex - the only CBD-only medicine formally registered with the TGA and the FDA. Recruitment is expected to commence in Q1, 2022.

Recently completed animal studies evaluating EMD-RX5 suggest that it has improved bioavailability compared to Epidyolex meaning it may deliver more CBD to a patient at equivalent prescribed doses. [3] Improved bioavailability means a higher active drug exposure is achieved for patients at lower ingested doses.

EMD-RX5 is expected to be suitable for multiple clinical indications and patient cohorts. Subsequently, EMD-RX5 will support many of Emyria's Real-World Evidence (RWE) guided drug registration programs including those currently running:

- **EMD-003** - a program targeting registration for an over-the-counter, low-dose CBD treatment for the temporary symptoms of psychological distress [4] and;
- **EMD-004** - a program targeting registration for a CBD treatment for the relief of symptoms associated with Irritable Bowel Syndrome (IBS) [5]

Emyria's proprietary Real-World Evidence (RWE) is robust clinical evidence with millions of data points collected with thousands of patients receiving longitudinal care at Emyria's clinical service subsidiary (Emerald Clinics). Insights from Emyria's RWE have guided each of Emyria's current drug registration programs. Emyria's RWE helps the Company identify which indications and patient cohorts respond favourably to certain cannabinoid treatment regimes. Thereby, ongoing analysis of Emyria's RWE is expected to identify further clinical indications and applications for EMD-RX5 as well as suggest other novel cannabinoid medicine development and registration opportunities.

GMP production of EMD-RX5 has now commenced. GMP (Good Manufacturing Practice) describes a set of principles and procedures, set by regulators, to help ensure therapeutic goods are of the highest pharmaceutical quality. GMP-grade product is a mandatory requirement for clinical trials supporting registration with major regulators.

The pivotal Phase 3 clinical trial for EMD-RX5 as a treatment for temporary psychological distress (EMD-003) is well advanced with recruitment expected to commence in early Q2, 2022. A site network to manage the trial has been engaged.

Emyria is targeting its first TGA submission by the end of 2022. Further clinical applications of, and global registration opportunities for, EMD-RX5 are in development. Further information will be provided to the market as this program advances.

Emyria's Managing Director, Dr. Michael Winlo said: *"We're delighted to commence Phase 1 human clinical trials for our proprietary ultra pure CBD formulation, now referred to as EMD-RX5.*

EMD-RX5 is the designated formulation supporting Emyria's first drug registration program guided by our proprietary Real-World Evidence - the EMD-003 program. Following our recent successful animal studies - comparing our formulation to Epidyolex - we also believe EMD-RX5 has the potential to become a registered treatment for multiple indications.

Given the speed and success of developing EMD-RX5, and ongoing insights provided by Emyria's RWE, Emyria is now evaluating other proprietary cannabinoid formulations and dose forms that may be suitable candidates as additional drug development programs for our expanding treatment pipeline targeting registration in Australia and the USA for large unmet needs.

We look forward to providing more updates on our Phase 1 and Phase 3 clinical trials as well as additional registration plans 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	**Lexi O'Halloran**	**Andrew Williams**
Managing Director	**Media/Investor Relations**	**Media Relations**
1300 436 363	**+ 61 (0) 404 577 076**	**+61 (0) 412 614 125**
mwinlo@emyria.com	lexi@janemorganmanagement.com.au	andreww@profilemedia.com.au

References

1. Maguire R, F, Wilkinson D, J, England T, J, O'Sullivan S, E: The Pharmacological Effects of Plant-Derived versus Synthetic Cannabidiol in Human Cell Lines. Med Cannabis Cannabinoids 2021;4:86-96. doi: 10.1159/000517120
2. Louis Bengyella, Mohammed Kuddus, Piyali Mukherjee, Dobgima J. Fonmboh, John E. Kaminski. Global impact of trace non-essential heavy metal contaminants in industrial cannabis bioeconomy. Toxin Reviews, 2021; 1 DOI: 10.1080/15569543.2021.1992444
3. See ASX announcement 15 Dec 2021
4. See ASX announcement 05 Jan 2021
5. See ASX announcement 15 Jun 2021

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.