

Emyria to benefit from Final TGA ruling on CBD medicines emphasising requirement for evidence

Highlights:

- Final decision from Australia's Therapeutic Goods Administration (TGA) confirms requirement for **product-specific safety and efficacy data to support registration** of low-dose CBD products (<150mg/day) as Schedule 3 medicines for all proposed doses and indications
- **Emyria Data** is one of the largest clinical-trial-grade data sets covering safety and efficacy data on over 3,000 patients for a wide range of clinical indications and CBD doses, including low-dose CBD as referenced in the TGA's Final decision
- **Emyria Data** is proprietary and valuable source of IP which is informing the launch of Emyria's first two drug development programs targeting TGA registration; EMD-003 (mental health) and EMD-004 (irritable bowel syndrome)
- Recently announced funds raised by Emyria will support the acceleration of pivotal clinical trials required as an important first step towards the registration of EMD-003 and EMD-004 with the TGA as Scheduled medicines

Emyria Limited (ASX: EMD) (Emyria or the Company), a data-backed drug development company, welcomes the final decision from the Australian Therapeutic Goods Administration (TGA) that upholds the strict requirements for high quality, product-specific, clinical evidence in order to obtain registration of low-dose CBD products as Schedule 3 medicines on the Australian Register of Therapeutic Goods (ARTG).

The TGA made its final ruling on Tuesday December 15, 2020 and clarified that "*applications to register a Schedule 3 low-dose CBD preparation on the ARTG would involve assessment of safety and efficacy data to support the proposed dose and indication.*" (Page 11 of Final Decision document available <https://www.tga.gov.au/node/935781>).

The TGA decision could allow patients to purchase formally registered low-dose CBD products as Pharmacist Only medications, for specific indications. Higher doses of CBD and other cannabinoid medicines would still require a prescription from a medical practitioner.



Emyria's strategy is to generate high quality, ethically-sourced real-world and clinical evidence, called **Emyria Data**. Emyria Data is generated within Emyria's Emerald Clinics from consenting patients and currently contains 2.6M, anonymised data points - and growing. Emyria Data covers patient demographics, clinical diagnoses, concomitant medications, adverse event monitoring, vital signs, validated clinical assessments, patient reported outcomes and more. As a result, Emyria Data is a unique source of IP and can provide insights into the safety and efficacy profiles of a wide range of CBD doses and formulations (including low dose CBD) and for a wide range of unmet needs.

Emyria Data is informing Emyria's first two data-backed and IP-supported drug development programs, both addressing widespread unmet needs. **EMD-003** is intended to address unmet mental health concerns and **EMD-004** is intended to address irritable bowel syndrome (IBS). Both programs are set to benefit from the TGA ruling and planning for the pivotal registration clinical trials is underway.

Emyria's Managing Director, Dr Michael Winlo, said: "Regulators play an important role ensuring medicines are safe and effective before they are available to patients which is why they require high quality clinical evidence for all new product registrations.

Since founding, Emyria has carefully gathered and curated one of the largest and most comprehensive, ethically-sourced, clinical data sets covering a wide range of CBD doses, clinical indications, validated clinical changes and safety data. This data is a source of unique insights and IP and strategically informs Emyria's own drug development programs.

As per a recently completed placement to strategic investors, the company is currently well funded to achieve registration milestones related to our first two drug development programs addressing major unmet needs EMD-003, focussed on mental health and EMD-004, focussed on irritable bowel syndrome (IBS). The TGA decision supports our strategy to pursue high quality, data-backed registration for our products."

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

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About Emyria (www.emyria.com)

Emyria Limited is a data-backed, drug development company targeting unmet needs. Emyria's drug development programs are focused on obtaining formal registration with major global regulators and are informed by insights generated from extensive analysis of **Emyria Data** - deep, ethically-sourced clinical and real-world evidence that is gathered with patients across Emyria's independent clinical services (**Emerald Clinics** - www.emeraldclinics.com.au), currently treating over 3,000 patients, and growing.

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.