ASX Announcement

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Emyria pursuing registration of EMD-003 in CY2021 to treat symptoms of anxiety, depression and stress

Highlights:

- Emyria seeks 2021 registration for EMD-003, a cannabinoid-based medicine to reduce symptoms of anxiety, depression and stress
- EMD-003 to benefit from recent TGA ruling on to down-schedule Australian registered low-dose CBD as a Schedule 3 Pharmacist-only medication
- Initial clinical evidence analysis and patent filing has been completed
- Pivotal human registration trials to commence in H1, 2021

Emyria Limited (ASX: EMD) (Emyria or the Company), a data-backed drug development company, will pursue the registration of **EMD-003** with Australia's Therapeutic Goods Administration (TGA) in 2021.

EMD-003 is Emyria's first cannabinoid-based medicine to have been developed following an extensive analysis of data gathered from its clinical subsidiary - **Emerald Clinics**.

Emerald Clinics' doctors provide long-term, individualised care for unresolved patient conditions. By tracking important clinical changes using a bespoke digital health platform, Emyria has created an ethical source of unique data covering a wide variety of patients, products and formulations. Analysis of these data reveal unique product and dose-response insights for certain patient populations and conditions.

The development of EMD-003 demonstrates that, as Emyria's database grows, it becomes an increasingly valuable source of high-quality clinical evidence and intellectual property with the potential to support multiple IP-backed drug registration programs.

In the first half of 2021, Emyria intends to commence the pivotal registration study for EMD-003 - a cannabinoid-based medicine focussed on unmet needs targeting the treatment of psychological distress and the symptoms of anxiety, depression and stress for certain patient populations.

Mental health is a rising global health challenge, particularly in the last 12 months. In the 2017-2018 National Health survey, mental health topped the list of chronic health conditions in Australia affected 4.8 million people, or 20.1% of all Australians(1). In any one year over 2 million Australians suffer from anxiety alone(2). Psychological distress, in particular, has been increasing in incidence.(3)

With the rising challenge of mental health, new safe and effective registered drug treatments are desirable. In 2018-2019, 4.3 million Australians received mental health related prescriptions including over 27 million antidepressant prescriptions,, the recommended first-line pharmacological treatment for anxiety(4). A recent internal analysis had revealed that more than 50% of Emerald patients present with moderate to severe depression, anxiety and / or stress as measured by validated clinical assessments.

The EMD-003 registration program, if successful, has been designed to deliver a new, registered medicine for the treatment of psychological distress and symptoms of depression, anxiety and stress.

TGA Registration plan:
To date, only 1 cannabinoid-based medicine has been formally registered with the TGA - GW Pharma's, Epidyolex - a CBD-only medicine for the "adjunctive therapy of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS)"(5). All other cannabinoid-based medicines are available only via Special Access Schemes, Authorised Prescribers or clinical trials.

On December 15, 2020, the TGA announced a final ruling that would allow low-dose CBD (<150mg) to be registered as a Schedule 3 medication, emphasising that all "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).(6)

While the TGA decision could allow patients to purchase registered CBD products as Pharmacist Only medications, high quality, dose-, product- and indication-specific clinical evidence is crucial for any registration effort. In light of this regulatory framework, Emyria is uniquely placed to utilise its large body of clinical data to assist in the registration of EMD-003 and other cannabinoid medicines.

In anticipation of the TGA ruling, Emyria conducted an in-depth analysis of its own data, published literature and patent landscape. Subsequently the Company filed unique IP (see ASX announcement 25 Nov 2020) which covers the use of specific doses of CBD at or below the 150mg dose for a set of medical indications and patient cohorts.

Emyria is now further analysing its data to refine the pivotal registration clinical trials which are expected to commence in H1, 2021. A final evidence package to support registration with the TGA is expected to be completed in H2, 2021.

In parallel to the TGA-registration plan described above, Emyria will also design its EMD-003 registration studies to meet the requirements of other global regulatory bodies. This approach will provide the company the ability to subsequently apply for EMD-003 pharmaceutical registration within other major markets and jurisdictions.

Sources:
1. https://www1.racgp.org.au/newsgp/clinical/mental-health-issues-increasing-among-australians
2. https://www.beyondblue.org.au/media/statistics
3. https://www.aihw.gov.au/reports/mental-health-services/mental-health-services-in-australia/report-contents/mental-health-related-prescriptions/prescriptions
4. https://www.nps.org.au/australian-prescriber/articles/drug-treatment-for-anxiety#r8
5. https://www.tga.gov.au/apm-summary/epidyolex
6. https://www.tga.gov.au/node/935781

Emyria's Managing Director, Dr Michael Winlo, said: *"Since our doctors are focussed on getting the best outcome for every patient, we gain unique insights into the performance of a wide range of products and doses across a diverse range of patients and conditions. By also taking our time with every patient and using our bespoke digital health platform, which also incorporates remote monitoring, we have built a high-quality and one-of-a-kind, clinical data asset.*

By analysing this data, we reveal unique insights and intellectual property that can guide and accelerate multiple drug registration programs, each one focussed on producing a registered medicine addressing a major unmet need once pivotal registration clinical trials are completed.

We're excited to pursue the pivotal registration study of EMD-003 with the TGA in 2021 and help tackle the growing global concern of mental health and, in particular, the symptoms of anxiety, depression and stress."

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. **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.