ASX Announcement

27/01/2021

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FDA position on RWE to guide CBD regulation opens pathway to US

Highlights:

- FDA leadership states *"real-world data (RWD) on CBD use and safety has a crucial role alongside data from other types of studies to fill in the current gaps in our understanding."*
- FDA leadership confirms they will evaluate *"CBD just like any other substance we regulate, under a regulatory framework defined by law and with rigorous scientific evidence as a basis for both our regulatory approach and information we communicate."*
- Emyria's unique real-world data asset is well positioned to help address specific evidence gaps in CBD medicine as articulated by the FDA
- Emyria's first drug development program - **EMD-003** - is directly informed by Emyria's proprietary RWD and IP
- EMD-003 to seek Australian registration as low-dose CBD Schedule 3 Pharmacist-only medication with FDA registration to follow successful registration

Emyria Limited (ASX: EMD) (Emyria or the Company), a data-backed drug development company, welcomes a recent perspective shared by the leadership of the Food and Drug Administration (FDA) - the major regulatory agency that approves medicines in the USA - which highlights the potential role of real-world data (RWD) to improve the understanding of the safety and uses of cannabidiol (CBD).

In an article titled Better Data for a Better Understanding of the Use and Safety Profile of Cannabidiol (CBD) Products (1) Dr Stephen Hahn, immediate past Commissioner of Food and Drugs (2) and Dr Amy Abernethy, Principal Deputy Commissioner (3) state:

> *"We think that real-world data (RWD) on CBD use and safety has a crucial role alongside data from other types of studies to fill in the current gaps in our understanding."*
>
> *...we strongly believe that RWD, when collected and analyzed using rigorous methods, can be important for moving the science forward—including by aiding hypothesis generation and by refining the design of follow-up studies. For example, RWD may identify new potential adverse events or subpopulations of CBD users that should be the focus of follow-up studies."* [See Appendix for additional points]

According to research conducted by US-based RWE company, Aetion, 75% of recent drug registration applications to the FDA now contain real-world evidence (RWE) as part of the evidence submitted. Up from 45% of applications in 2019, just one year prior. (4)

Emyria's RWD-generating care model

Since founding, Emyria has been collecting high quality **real-world data (RWD)** with patients seen through its clinical subsidiary - **Emerald Clinics**.

As outlined in Emyria's prospectus in January 2020: *"A core component of the Emerald Care model is the capture of comprehensive real-world data (RWD) from consenting patients that can be used as real-world evidence (RWE) to support innovation across the cannabinoid medicine industry."*

Each patient cared for at Emerald completes a regular series of validated clinical assessments. Data is entered into a bespoke, "trial-grade" digital health platform. These data document an individual's primary diagnoses, symptoms and other important clinical data such as concomitant medications. During treatment, the platform helps capture clinical changes, quality of life changes and also helps identify and track adverse events. Collectively, this data becomes robust and ethically-sourced real-world data (RWD) which can become high quality real-world evidence (RWE) to inform what products and dosages are safest and most effective.

Emyria's unique RWD now covers over 3,000 patients and is constantly growing in patient numbers and longitudinally. Emyria Data provides insights into specific patient populations, clinical conditions, products, formulations and dose responses. Emyria Data can help improve care decisions, is a source of intellectual property and can support multiple drug development programs.

Emyria's RWD- and IP-backed drug development programs

Emyria's first program, **EMD-003**, arises directly from the insights gained from rigorous analysis of **Emyria RWD**. EMD-003 will seek registration of a specific cannabinoid treatment for a defined group of patients (ie. "subpopulation") with symptoms of psychological distress and the symptoms of anxiety, depression and stress. Pivotal registration studies are being designed for EMD-003 from Emyria RWD outcomes. EMD-003 is seeking registration with the TGA and, if successful, will pursue registration with other global regulators such as the FDA.

[*See ASX announcement 05 Jan 21*]

Emyria believes the increasing interest and support for high quality RWE from the FDA, particularly in the field of cannabinoid medicines, bodes well for the company's strategy to use it's proprietary data platform and unique RWE assets to inform and support multiple drug registration programs targeting unmet needs.

Emyria's Managing Director, Dr Michael Winlo, said: *"We're encouraged, but not surprised, by the FDA leadership's strong support for carefully collected RWD to help improve our understanding of cannabinoid medicines specifically. Dr Amy Abernethy has been a pioneer in RWE as a key leader at Flatiron Health prior to joining the FDA. This recent FDA leadership perspective highlights the value the FDA places on high-quality RWD but also reinforces their strict standards for high quality clinical evidence to support drug registration.*

Since our founding, Emyria has been using the unique regulatory circumstances in Australia to gather what we now believe to be the largest and highest quality RWD set on pharmaceutical grade cannabinoid medicines in the world. We are now using this data to launch our own drug development and registration programs targeting major unmet needs and intend to use our RWD and supporting trial data to seek registration with the TGA and then other global regulators, like the FDA."

EMD-003 targeting unmet needs in mental health

EMD-003, Emyria's first drug program, will target 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.(5) In any one year over 2 million Australians suffer from anxiety alone.(6) Psychological distress, in particular, has been increasing in incidence.(7)

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.(8) A recent internal analysis had revealed that more than 50% of Emerald Clinics' patients present with moderate to severe depression, anxiety and / or stress as measured by validated clinical assessments.

Pivotal registration trials for EMD-003 are expected to commence in H1, 2021 with submission to the TGA planned for H2, 2021.

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

For further information:

Dr Michael Winlo
Managing Director
(08) 6559 2800
mwinlo@emyria.com

Lexi O'Halloran
Investor Relations
+ 61 (0) 404 577 076
lexi@janemorganmanagement.com.au

Andrew Williams
Media Relations
+61 (0) 412 614 125
andreww@profilemedia.com.au

REFERENCES

[1]https://www.fda.gov/news-events/fda-voices/better-data-better-understanding-use-and-safety-profile-cannabidiol-cbd-products
[2]Prior to the FDA, Dr Stephen Hahn was a practicing clinician / scientist at the Texas Medical Centre
[3]Prior to the FDA, Dr Amy Abernethy was Chief Medical Officer at Flatiron Health, a RWE company that was acquired by Roche for $1.9B USD in 2018
[4] **The role of real-world evidence in FDA approvals** (eBook) - https://aetion.com Accessed 26 Jan 21
[5]https://www.aihw.gov.au/reports/mental-health-services/mental-health-services-in-australia/report-contents/mental-health-related-prescriptions/prescriptions
[6] https://www.healthdirect.gov.au/irritable-bowel-syndrome-ibs
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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.

Appendix - more from the FDA Leadership article.

Guiding principles for FDA's work in this area include the following:

- Research projects should contribute, where possible, to the development of more sophisticated data infrastructure for understanding the safety and quality of CBD products.
- Research projects should yield information that helps us refine future studies—for example, by identifying potential adverse events or subpopulations that are most important to study further.
- Research projects should be designed with the goal of complementing existing work by other public health agencies, such as NIH and SAMHSA, as well as other stakeholders. States provide an important laboratory for novel data collection and analysis. The FDA projects should build on existing efforts at the state and national level to incorporate data from poison control centers, emergency departments, and other potential sources of information about adverse events related to CBD products.

Challenges in current capabilities for collecting data regarding the use and safety of CBD

- Much of the existing data on CBD use in the general population comes from spontaneously reported adverse events (e.g., from poison control centers), but more systematic data collection and analysis will be crucial for understanding relative safety risks.
- Rates of CBD use, and rates of use of specific CBD products, are poorly understood. What is the denominator of risk for adverse events in the population taking CBD? What specific populations have the highest CBD exposures and what specific products are frequently used? What other products, such as over-the-counter or prescription drugs, are used alongside CBD products? Are there risks associated with interactions between CBD products and other products, beyond those that have already been identified and communicated by the FDA?
- Data collection systems may not yet have specific codes that can precisely identify specific CBD products.
- Longitudinal studies (i.e., studies that provide data about the health of subjects over an extended period of time) are needed to understand long-term health effects of CBD use.

Research projects to address current challenges in the collection and analysis of CBD-related data

- In the coming months, the FDA intends to develop and refine plans for research projects that use the following strategies, among others, to address the gaps in current CBD data research capabilities:
- Work with existing and emerging data systems (e.g., poison control databases, electronic health records, opt-in consumer/patient registries) to enable precise identification of CBD products that may be associated with reported adverse events through appropriate coding, data curation, and other means.
- Evaluate approaches to link adverse event data with CBD product sampling and testing data.
- Collaborate on the development and evaluation of systems and methods, such as an open, opt-in registry for users of CBD, to gain a better understanding of safety outcomes of interest and incorporate data from other sources.
- Evaluate the use of market-research data and other data sources that provide insights on the use of specific CBD products in different populations.
- Evaluate use of data linkage approaches to provide insights about safety risks that may appear across time while protecting the privacy of patients and consumers.
- Evaluate the value of combining multiple research and data approaches to synthesize an aggregate view of CBD safety and quality across the market and across time.
- Evaluate which strategies are best for safety and quality monitoring for different types of CBD products.