25/11/2020

Emyria launches drug development program focused on mental health based on analysis of its Real-World Evidence

Highlights:

- **Emyria launches drug development program focused on mental health following deep analysis of its Real-World Evidence (RWE) generated from over 3,000 patients**
- **Emyria RWE has identified a unique dose range of cannabidiol that significantly reduces anxiety and stress symptoms in a specific patient patient population treated across Emyria's clinical service subsidiary, Emerald Clinics**
- **New therapeutic approach will focus on the growing mental health burden which cost the Australian health system alone, $9.9B AUD in 2017-2018[1]**
- **Emyria's data driven drug development model has potential to be replicated in new clinical indications and with new unregistered or repurposed medicines**
- **Development pathway and approval strategy underway to maximise commercial potential of the Emyria therapeutic approach**

Emyria Limited (ASX: EMD) (Emyria or the Company), a company that accelerates treatment development for patients with unmet needs based on its Real-World Evidence (RWE) insights, is pleased to announce the launch of its initial drug development program focused on mental health.

The decision to launch Emyria's drug development program was made following a deep, longitudinal analysis of Emyria's extensive RWE data assets which have been co-developed with patients that have been treated by Emyria's *Emerald Clinics* service. The analysis revealed statistically significant dose-response data in a target patient population using a series of globally validated mental health measures (including DASS-21 and BPI outlined below). These data insights effectively replace the need for exploratory therapeutic clinical trials, and provide quality safety and efficacy data that will allow registration trials to be accelerated as the effective dose range and target patient population has now been identified from the aggregated patient usage data.

Data insights

The RWE insights have been generated from statistical analysis from more than 3,000 anonymised patients that have been carefully clinically monitored at *Emerald Clinics*. As is typical, each patient has completed a series of validated clinical assessments to clarify diagnosis, monitor for changes to clinical signs, symptoms, quality of life, precise treatment dose taken, adverse events and concomitant medications to name a few. On average, over 150 data points are collected per visit from each patient.

As outlined in Figure 1, below, patients in the cohort analysis were regularly administered the DASS-21 (Depression Anxiety, Stress Scale - 21 elements). This test is a quantitative measure of distress. It examines three seperate, but interrelated areas: depression, anxiety and stress. Each of these three subscales also includes various items ranging from skeletal muscle effects to situational anxiety and nervous arousal for example. Data generated from the study analysis showed highly statistically significant improvements in the anxiety component of patients' DASS-21 scores ($P<0.001$) when treated with selected doses of cannabidiol. This is particularly pertinent in the sub-population treated, all of which were not able to improve their anxiety measures using standard of care treatments prior to their referral to *Emerald Clinics.*

[1] https://www.aihw.gov.au/reports/mental-health-services/mental-health-services-in-australia/report-contents/summary-of-mental-health-services-in-australia

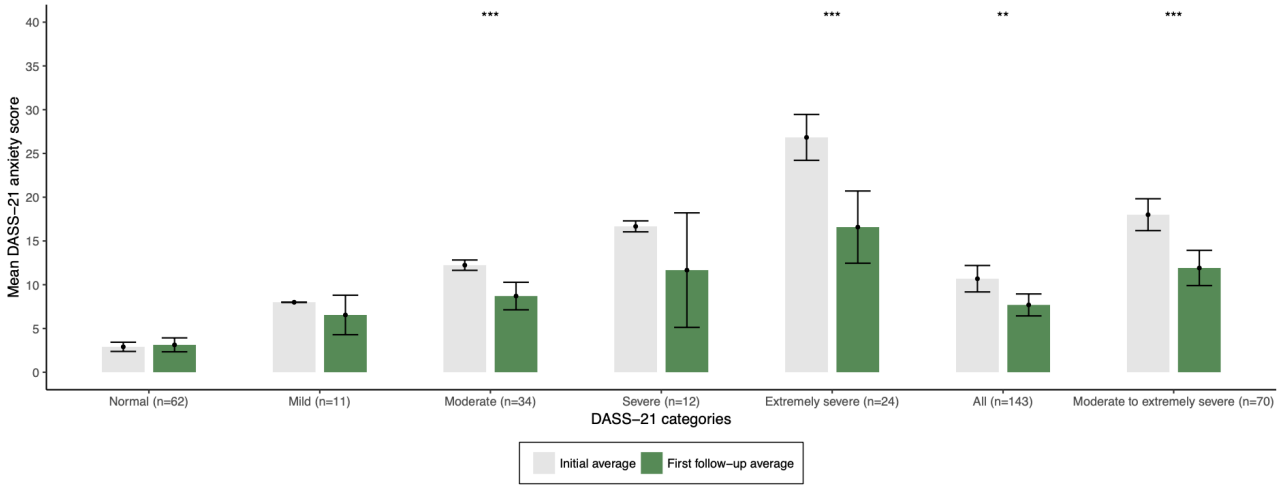

Figure 1: Mean anxiety scores, as measured via DASS-21 for target patient cohort with at least one follow-up visit (n =143). Chart reveals statistically significant improvement in anxiety for "moderate to extremely severe" segment. (** = $p < 0.005$, *** = $p < 0.001$).

The patient cohort was separately monitored for changes in average Brief Pain Inventory (BPI) scores as outlined below in Figure 2. BPI is a self-reported assessment, modelled after the McGill Pain Questionnaire, which provides information on the intensity of pain (sensory dimension) and the degree to which pain interferes with one's function (reactive dimension). It also asks questions about pain relief, pain quality, and the patients' perception of the cause of pain. BPI has become one the most widely used measurement tools for assessing clinical pain and has been used in hundreds of studies globally.

Data generated from the study analysis showed highly statistically significant improvements in patients' BPI scores ($p < 0.001$) when treated with selected doses of cannabidiol in the target cohort of patients. For a large proportion of patients treated, chronic pain had been a primary complaint lasting more than 5 years.

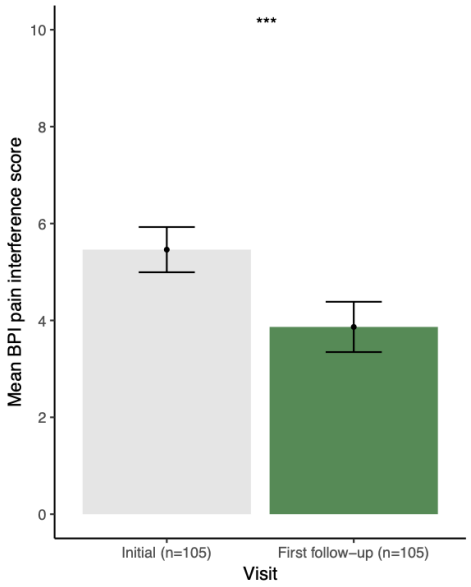

Figure 2: Mean pain interference scores by visit for the subset of target cohort presenting with chronic pain (n =105). Chart reveals statistically significant improvement in "pain interference" ($p < 0.001$) in target cohort using target treatment.

Data analysis and an extensive literature and patent review also informed the submission of a provisional patent to support commercialisation. Work will commence immediately to identify partners and suppliers.

Emyria's Managing Director, Dr Michael Winlo, said: "*We're very enthusiastic about the launch of our own evidence-based drug development program after an extensive review of the IP landscape, published literature and, of course, our own clinical evidence. This work has identified multiple, unique opportunities to develop treatments for specific mental health concerns as well as novel IP, which we have protected.*

We are also well placed to rapidly register these treatments given the unparalleled access we have to large patient populations across our independent clinical network, the clinical-trial grade data systems and remote monitoring technologies we have developed and our in-house expertise in data analysis, clinical trial design and drug registration. We expect this initial program to increase the availability of registered drug options for patients with mental health concerns and develop significant shareholder return in a highly capital efficient manner.

Mental health is a growing global health concern affecting many of our current patients and this drug development program compliments our recent partnership with Mind Medicine Australia focussing on the development of new treatment options for patients with major mental health concerns.

We look forward to updating the market with our progress towards registration and commercialisation of this program while we support our current partners to advance their own registration programs."

Emyria's first end-to-end drug development program will encompass a package of clinical evidence, intellectual property (IP) and strategically developed clinical trial protocols. The program is designed to support the registration of a specific cannabinoid-based medicine for a specific mental health indication with the Therapeutic Goods Administration's (TGA) Australian Register of Therapeutic Goods (ARTG).

Currently, most medicinal cannabis products available in Australia are "unapproved therapeutic goods", which means they have not been assessed by the TGA for quality, safety or effectiveness. Therefore, most of these products can only be accessed via Special Access Schemes (SAS) or from Authorised Prescribers. A successfully registered treatment would be accessible to patients via routine prescription or, if the TGA allows, over-the-counter pathways, representing a significant potential market opportunity.

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 creates clinical evidence that accelerates the registration of new treatments for patients with unmet needs. Emyria achieves this by analysing the high quality clinical data gathered from its specialist clinical network – Emerald Clinics (www.emeraldclinics.com.au) – and turning that into Real-World Evidence (RWE), unique IP and differentiated treatment development programs. Emyria's data supports treatment registration by providing unique, real-world insights into the safety, quality and efficacy of unapproved treatments, in real patients in the community. Emyria can also support registration activities by leveraging its independent clinics, unique remote patient monitoring technologies, clinical-trial-grade data platforms and care models. Emyria's treatment development programs can be pursued independently or with partners. Once treatments are registered with an official regulator, they can become available to a much wider population of patients via routine prescription pathways allowing Emyria to focus on

accelerating the development of the next unregistered treatment.

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.