ASX Announcement

15/06/2021

emyria
myriad data.
individual care.

Emyria advances EMD-004 program towards registration

Highlights:

- Emyria has filed additional **patents** supporting its EMD-004 drug development program targeting **Irritable Bowel Syndrome (IBS)**

- Emyria's patents were filed after signal **analysis of Emyria's clinical data (Emyria Data)**, one of the largest, trials-grade clinical registries for medicinal cannabis, and an extensive review of the global literature and patent landscape

- Emyria's patents cover unique dose strengths and formulations, believed to be most effective in treating a range of IBS-related symptoms including:
  - **CBD-only formulations** which could support a Schedule 3, over-the-counter registration program in Australia and;
  - **CBD and THC** containing formulations which could support higher Schedule applications and international registrations including US FDA

- There are currently no approved drug treatments for IBS which affects around 11% of the population globally and is a significant unmet need [1]

Emyria Limited (ASX: EMD) (Emyria or the Company), a drug development and clinical services company, is pleased to announce further intellectual property (IP) has been filed in support of its EMD-004 drug development program targeting the symptoms of irritable bowel syndrome (IBS). *(See ASX release 03 Dec 2020)*

IBS is a group of symptoms that occur together, including repeated pain in your abdomen and changes in your bowel movements, which may be diarrhea, constipation, or both. With IBS, you have these symptoms without any visible signs of damage or disease in your digestive tract which is why the condition can be challenging to diagnose and treat. [2]

IBS affects around 11% of the population globally and is a significant unmet need often associated with greater levels of anxiety and lower quality of life measures. There are currently no approved drug treatments for IBS.

The new IP was filed after extensive analysis of Emyria's proprietary clinical data (Emyria Data). Emyria Data is deep clinical data collected with consenting patients who obtained relief from their IBS condition while being treated at Emyria's wholly-owned, nationwide clinical subsidiary - Emerald Clinics.

EMD-004 is Emyria's second drug development program to be launched following analysis of Emyria Data. A large observational study involving IBS patients is currently underway across Emerald Clinics.

Emyria Data is one of the largest and highest quality real-world clinical data sets in the world covering the long-term safety and efficacy of pharmaceutical-grade cannabinoid-based medicines prescribed for thousands of patients with unmet needs.

Analysis of Emyria Data has also supported the patents and clinical development strategy of Emyria's leading EMD-003 program which is currently progressing towards registration as a Schedule 3, over-the-counter cannabinoid-based medicine. *(See ASX release 07 Apr 2021)*

The high quality, validity and utility of Emyria Data was recently demonstrated by a unique piece of analysis performed with global clinical research organisation, IQVIA (NYSE: IQV). *(See ASX release 07 June 21)*

Emyria's Managing Director, Dr. Michael Winlo says: *"A major benefit of Emyria's high quality, real-world clinical data is that it allows us to frequently and confidently file differentiated and strongly developed patents that support and defend our parallel-running drug development programs.*

Just like EMD-003, our first cannabinoid medicine drug development program targeting psychological distress, EMD-004 is now well defined with patents filed covering our unique dose response insights for specific patient populations.

Filing IP of this kind is crucial in helping differentiate, and ultimately register, cannabinoid-based treatments in major markets around the world. This is what large pharma look for in drug development programs.

We are constantly analysing our proprietary clinical data which was recently validated in a data linkage project with global clinical research organisation, IQVIA. In addition to further IP, our ongoing analysis allows us to launch new drug development programs in parallel, each targeting major, global, unmet needs."

The company will provide further updates on EMD-003, EMD-004 and future drug development programs as registration activities and analysis continues.

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

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REFERENCES

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3921083/
[2] https://www.niddk.nih.gov/health-information/digestive-diseases/irritable-bowel-syndrome/definition-facts

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.

Emyria's first drug development program, **EMD-003** is targeting unmet needs in mental health. Specifically psychological distress and the symptoms of anxiety, depression and stress.

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.