

Emyria and Cann Group to partner on Schedule 3 medicine CBD product registration



Highlights:

- Collaboration agreement aims to **accelerate** the registration of a **Schedule 3, over-the-counter, cannabidiol (CBD) medicine** in Australia
- Emyria's **EMD-003** drug development program will incorporate Cann Group's newly acquired **Gelpell™ microsphere** formulation technology
- Partnership provides **potential significant cost and speed advantages** to registration
- **Successful registration** with the Australian Therapeutic Goods Administration (TGA) opens the path to **registration opportunities overseas**
- **Emyria and Cann Group** will negotiate product commercialisation arrangements prior to a regulatory approval application being submitted

Emyria Limited (ASX: EMD) (Emyria) and **Cann Group Limited (ASX: CAN)** (Cann Group) are pleased to announce a collaboration agreement to seek accelerated registration of a unique, low-dose, CBD-only capsule with Australia's Therapeutic Goods Administration (TGA).

Successful registration as a Schedule 3 medicine would result in an **over-the-counter, pharmacist-only CBD medicine**.

Under the agreement, **Emyria's EMD-003** drug development program will use Cann Group's proprietary **Gelpell microsphere technology**, as the basis for seeking a Schedule 3 registration for treating unmet needs in mental health. A joint project committee will be formed to oversee the allocation of registration costs and the development of commercialisation agreements.

Cann Group recently acquired the rights to the technology via the purchase of the Satipharm group of companies (*as previously announced by Cann Group on 15 February 2021*), which has commercialised a CBD product utilising the technology. Cann Group plans to incorporate manufacturing of the microsphere formulation in its new production facility currently under construction near Mildura.

The collaboration capitalises on a number of **important milestones** that have already been met:

- **Phase 1 trials already completed** for 10mg and 100mg doses of the Satipharm capsule
- **Satipharm CBD** has been shown to have **3.5 times greater bioavailability** compared to oil preparations (at 100mg)[1]
- **Long-term stability testing undertaken** (and continuing)
- **Emyria** already **has real-world data** on more than **170 patients** taking the Satipharm CBD capsule
- **Emyria** has **prepared protocols for pivotal clinical trials** for target indication

Emyria's experienced drug development and clinical team will lead the registration program.

Pivotal clinical trials are in advanced stages of planning and are being **guided by insights from Emyria Data**, which includes robust safety, efficacy and patient preference data for more than 3,500 patients treated at Emyria's Emerald Clinics.

Emyria's Managing Director, Dr. Michael Winlo, said: *"This partnership greatly accelerates Emyria's EMD-003 drug development program by combining Emyria's unique clinical data and drug development expertise with Cann Group's best-in-class CBD delivery technology.*

Satipharm CBD has already completed robust stability testing as well as Phase 1 clinical trials as required by the TGA. This allows us to move straight to pivotal clinical outcomes trials saving significant time and money. An experienced Regulatory Consultant has already been engaged to manage the TGA submission.

Further, at Emyria, we already have deep insights into how the Satipharm product performs clinically, having written over 400 Satipharm prescriptions to more than 170 patients. This de-risks the pivotal clinical outcomes trials required as an important first step towards registration with the TGA."

Cann Group's CEO, Peter Crock, said: *"Cann Group is pleased to partner with Emyria to accelerate the registration of a Schedule 3 medicine.*

We anticipate there will be a large patient demand for a TGA registered CBD medicine that is convenient to patients and demonstrates the highest standards of quality, safety and efficacy.

We believe our microsphere technology - with improved bioavailability – fits well with Emyria's drug development programs, which have the potential to accelerate registration with the TGA due to Emyria's extensive real-world data, national clinical site network and previous drug development experience.

We are also working to bring the Gelpell pharmaceutical GMP manufacturing line to Cann's Mildura production facility which, when commissioned at the end of this calendar year, will become the largest cannabinoid medicine production facility in Australia."

EMD-003 targeting a major unmet need

EMD-003 is targeting 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 affecting 4.8 million people, or 20.1% of all Australians[2]. In any one year over 2 million Australians suffer from anxiety alone.[3] Psychological distress, in particular, has been increasing in incidence.[4]

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.

The collaboration, if successful, will deliver a new, registered medicine for the treatment of psychological distress and symptoms of depression, anxiety and stress.

Cann Group's proprietary Gelpell technology

Cann Group's microsphere formulation embeds CBD in seamless gelatine microspheres (tiny beads) which have a dimension of 2 mm or less and are packed in hard gastro-resistant capsules. The active ingredients – cannabinoids - are bound and protected by a three-dimensional natural gelatine matrix in each bead. These gelatine beads protect the CBD contained in them from heat, light and oxygen, exhibiting improved stability and bioavailability of cannabinoids compared to other formulations.

In a final dose form, these beads are placed in gastro-resistant capsules which protect the beads from acid in the stomach. When swallowed, the beads disperse throughout the intestine, where they are absorbed by the body into both the bloodstream and the lymphatic system, minimising the impact of the first pass metabolism in the liver and contributing to improved bioavailability.

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

References

[1] Atsmon J, Heffetz D, Deutsch L, Deutsch F, Sacks H. Single-Dose Pharmacokinetics of Oral Cannabidiol Following Administration of PTL101: A New Formulation Based on Gelatin Matrix Pellets Technology. Clin Pharmacol Drug Dev. 2018 Sep;7(7):751-758. doi: 10.1002/cpdd.408. Epub 2017 Nov 10. PMID: 29125702.

[2] <https://www1.racgp.org.au/newsgp/clinical/mental-health-issues-increasing-among-australians>

[3] <https://www.beyondblue.org.au/media/statistics>

[4] <https://www.aihw.gov.au/reports/mental-health-services/mental-health-services-in-australia/report-contents/mental-health-related-prescriptions/prescriptions>

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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.

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.

About Cann Group

Cann Group Limited (ABN 25 603 949 739) is building a world-class business focused on breeding, cultivating, manufacturing and supplying medicinal cannabis for sale and use within Australia and for approved overseas export markets. The company has established research and cultivation facilities in Melbourne and is developing a state-of-the-art cultivation facility near Mildura, Victoria. Cann Group has executed collaboration agreements that have enabled it to establish a leading position in plant genetics, breeding, extraction, analysis and production techniques required to facilitate the supply of medicinal cannabis for a range of diseases and medical conditions. The Company is commercialising a range of imported and locally sourced and manufactured medicinal cannabis products. Learn more about Cann Group at www.canngrouponlimited.com