CANN GROUP LIMITED

ASX ANNOUNCEMENT

13 August 2021

Cann Group to utilise proprietary technology platform for Schedule 3 CBD product registration program

13 August 2021 - Cann Group Limited (ASX: CAN) (**Cann**) today confirmed that it is proceeding with a registration program aimed at securing Australian approval for a Schedule 3 (**S3**) over-the-counter CBD-only product based on Cann's proprietary Gelpell microsphere technology. This follows an announcement earlier today that a registration collaboration agreement with Emyria Limited has been formally terminated by mutual consent.

Rights to the patented Gelpell technology were acquired by Cann as part of the acquisition of the Satipharm business in March of this year. The Satipharm CBD 50mg capsules will be the first in a planned portfolio of medicinal cannabis products to assist a wide range of Australian patients and consumers.

Cann will now resume an internal development program building on clinical trials already undertaken by Satipharm.

These include a Phase I clinical trial of the Satipharm CBD capsules in which results demonstrated the safety and high performance of the oral capsule technology, including the superior delivery profile of cannabidiol (**CBD**) compound to trial subjects. This clinical trial measured the bioavailability of CBD showing substantially higher results for the Satipharm capsules than the reference drug product used as a comparator, Sativex – a market-leading, commercially available cannabinoid oral spray produced by GW Pharmaceuticals. This trial has been published in an international, peer-reviewed medical journal, *Clinical Pharmacology in Drug Development* (CPDD).[1]

A Phase II clinical trial of the Satipharm CBD capsules showed significantly reduced monthly seizure frequency in the treatment of children suffering from refractory, or treatment-resistant epilepsy when the Satipharm capsules were added to current medications. The treatment was generally well tolerated and the median reduction in seizures was 81.9% following 12 weeks of treatment. The results of this second trial have been published in the medical journal *Epilepsy & Behavior.*[2]

Cann expects to make announcements in the near future regarding the proposed indication and the clinical program to support product registration of the Satipharm 50mg CBD capsules as an S3 'Pharmacist Only Medicine' in Australia. The protocol design for this next clinical trial will be for a pivotal Phase III study, to produce data that supports regulatory approval by the Therapeutic Goods Administration (**TGA**).

[1] Atsmon, J. et al. "*Single-Dose Pharmacokinetics of Oral Cannabidiol Following Administration of PTL101: A New Formulation Based on Gelatin Matrix Pellets Technology*." Clinical Pharmacology in Drug Development 7 (2018)

[2] Mitelpunkt, A et al "*The safety, tolerability, and effectiveness of PTL-101, an oral cannabidiol formulation, in pediatric intractable epilepsy: A phase II, open-label, single-center study",* Epilepsy & Behaviour 98 (2019) 233-237

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Cann Group's CEO, Peter Crock, said the company remains focussed on submitting a registration application for the Satipharm S3 CBD product as soon as possible, with the aim of securing an approval by the end of calendar year 2022.

"Cann's unique formulation and delivery platform enables us to develop a CBD-only product that has superior stability and bioavailability properties and a medicine presentation that will be familiar to consumers and pharmacists.

"Satipharm CBD capsules were one of the first medicinal cannabis products available to approved patients in Australia (under the Special Access Scheme) and have been successfully used in a variety of medical conditions since 2017. Satipharm CBD products are currently sold over-the-counter at major pharmacies and health food retailers in the UK and Cann is in discussions with major healthcare companies in relation to global distribution rights to the product.

"Our international expansion plans for the Satipharm CBD products prioritise Australia as a key market, where consumer interest and demand for CBD-only products continues to grow. The TGA assessment and approval process is rigorous and provides Australian consumers with a high degree of confidence around quality and safety.

"Our recent institutional placement secured the funding necessary for Cann to independently pursue our registration plans and to seek to be first to market in Australia with a TGA approved product."

Authorised for release by the Board of Directors of Cann Group Limited.

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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. Cann also owns Satipharm, a Europe-based business exclusively licensed to manufacture, develop and market the proprietary Gelpell delivery system for cannabinoids. Cann has established research and cultivation facilities in Melbourne and is developing a state-of-the-art cultivation and manufacturing facility near Mildura, Victoria. Cann Group has established 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 at: www.canngrouplimited.com | www.satipharm.com