

ASX ANNOUNCEMENT

15 February 2022

Cann to begin recruitment for cannabidiol (CBD) phase 3 clinical trial for short term sleep disturbances

15 February 2022 – Cann Group Limited (ASX: CAN) (**Cann** or the **Company**) announced today that it will begin recruiting patients next month for a phase 3 clinical trial examining the efficacy of its proprietary CBD-Satipharm capsule for the short-term treatment of sleep disturbances and quality of life outcomes.

The clinical trial is a randomised, double blind, placebo-controlled study and part of a registration program undertaken by Cann to secure an Australian approval for a Schedule 3 (**S3**) over-the-counter cannabidiol (**CBD**) product.

At least 212 patients will be randomly placed into four cohorts receiving one of three different doses of the Satipharm CBD formulation, or a placebo. Clinical trial sites will be in most major capital cities in Australia. Patients will be treated for four weeks, and results of the trial are anticipated to be released later in 2022, in line with Cann's S3 registration program.

Earlier clinical trials involving Satipharm CBD capsules have been successful; a previous phase 1 clinical trial of the Satipharm CBD capsules demonstrated the safety and high performance of the oral capsule technology, including the superior absorption of CBD by trial subjects compared to the leading medical cannabis product in the market,¹ and a phase 2 clinical trial of the Satipharm CBD capsules showed them to be efficacious as an add-on therapy in the treatment of paediatric, intractable epilepsy.²

During the 2021 financial year, Australians spent approximately \$97 million on pharmacy-supplied over-the-counter sleep disturbance products.³

Dr Dev Banerjee, a leading sleep and cannabinoid physician in Australia who, with other sleep specialists, has assisted with the clinical trial design, said while strong anecdotal evidence exists to support the efficacy of CBD for patients struggling to achieve sleep, it is extremely important that this is validated by well-designed clinical trials.

"Many products and supplements currently promoted as sleep therapies are not supported with rigorous clinical data, so it would be a great benefit to have a proven, registered CBD treatment available on a pharmacy-only basis."

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;7(7):751–8

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

³ MIDAS® sales data, Australia 2020-2021

Cann's CEO, Mr Peter Crock, said the trial will be the first in Australia using the advanced Satipharm delivery technology which has previously been shown to result in improved bioavailability of CBD.

"Our clinical evaluation program addresses an important and growing market and – assuming we generate positive outcomes – offers a relatively fast route to registration approval."

The Satipharm CBD capsules will be produced at Cann's new manufacturing facility near Mildura which has recently been audited by the TGA as part of the process to obtain a GMP licence for that facility.

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 a proprietary delivery system for cannabinoids. Cann has established research, cultivation and GMP manufacturing 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.canngrouponlimited.com | www.satipharm.com