

AusCann receives ethics approval to commence clinical trial and will start product distribution in Australia

31 March 2020 – Medicinal cannabis pharmaceutical company **AusCann Group Holdings Limited** (ASX: AC8) ('AusCann' or 'the Company') is pleased to announce it is ready to commence its first clinical evaluation at an independent clinical site - Nucleus Network. At the same time, the Company's hard-shell capsule products are now available for prescribing by authorised doctors in Australia.

AusCann intends to conduct a randomised, open-label, cross-over Phase I bioavailability study trial in healthy volunteers to evaluate the pharmacokinetics of its hard-shell capsules at two different dose strengths of balanced THC:CBD formulations. AusCann's hard-shell capsule formulation is a unique presentation for cannabinoid medicines, and the study will provide key exposure information to inform dose selection.

All the required approvals to run the study have been obtained, including the ethics committee approval. The study will be open for recruitment during April through Nucleus Network. Following participant recruitment, the study is scheduled to start on April 20, 2020. While AusCann is committed to executing the study per the defined timeline, the health and safety of study participants is a priority. AusCann and Nucleus Network will monitor developments around COVID-19 and if need be will adjust the study timelines accordingly.

Concurrently with the clinical study and following interest from medical practitioners, AusCann has made the dose-controlled capsules commercially available for prescription to patients in Australia through the Therapeutic Goods Administration's (TGA) Special Access Scheme and Authorised Prescribers. The Company has received all appropriate notifications from the TGA, commercial inventory of the hard-shell capsules was shipped to distribution partner CH2 and is now authorised for distribution in Australia.

AusCann CEO, Mr Ido Kanyon commented: "AusCann has developed standardised cannabinoid-based formulations in a dose-controlled capsule. The capsules have been tested in a lab setting and demonstrated to be reliable, stable and deliver a consistent controlled dose of the formulations. We are now excited to commence the clinical evaluation of the capsules to demonstrate the product's benefits for patients."

"We are extremely pleased to have reached this milestone and that our capsules are now available for prescription. These results will build the clinical evidence supporting the unique benefits of AusCann's capsules, whilst enhancing the medical acceptance of cannabinoid-based medicines for the benefit of patients in Australia."

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This ASX announcement was authorised for release by the Board of AusCann.

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ABOUT AUSCANN

AusCann Group Holdings Limited (ASX:AC8) is an Australian-based pharmaceutical company focused on the development, production, and distribution of cannabinoid-based medicines within Australia and internationally. AusCann transforms the way Medicinal Cannabis is dispensed today by making standardised dose-controlled cannabinoid-based pharmaceutical products and clinical evidence accessible to patients, physicians and healthcare providers. AusCann enables physicians to treat their patients with a reliable, stable and standardised cannabinoid-based pharmaceutical product, monitor treatment results and adjust treatment algorithms using a portfolio of products and formulations.

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