

AusCann completes clinical evaluation recruitment and commences subject dosing

28 April 2020 – Medicinal cannabis pharmaceutical company **AusCann Group Holdings Limited** (ASX: AC8) ('AusCann' or 'the Company') is pleased to announce the completion of recruitment and commencement of its first clinical evaluation at an independent clinical site – Nucleus Network.

AusCann is conducting a randomised, open-label, cross-over Phase I study to evaluate the pharmacokinetics of a single dose of two formulations of orally administered THC/CBD combination in healthy volunteers. The primary endpoints of the study are the assessment of the pharmacokinetics of THC, CBD and the main active metabolite of THC (11-hydroxy-THC), after oral doses of 2.5mg:2.5mg and 10mg:10mg of THC:CBD.

The target number plus reserves, of healthy male and female volunteers have been recruited. One study arm of 14 participants will receive a 2.5mg:2.5mg THC:CBD capsule with cross-over to oil comparator, while the second study arm of 14 participants will receive a 10mg:10mg THC:CBD capsule with a cross-over to comparator, with a 14-day washout period between treatments. Dosing of first subjects is complete.

The study will provide key exposure information to inform dose selection and provide medical professionals with relevant information to assist in prescribing the unique hard shell capsule. The combination of a regulated dose format and formulation information provides both doctor and patient with greater control over their treatment regime.

AusCann CEO Mr Ido Kanyon said "We are very excited to be progressing this important study to provide evidence-based information to medical professionals about our unique hard shell capsule. This is the first of many studies planned by AusCann to better understand and prove the benefits of using controlled dose medicinal cannabis for medical treatment."

The study is expected to be completed within this calendar year. While AusCann is committed to executing the study per the defined timeline, the health and safety of study participants is a priority in light of the current COVID-19 pandemic. AusCann and Nucleus Network continue to monitor developments around COVID-19, and if need be will adjust the study timelines accordingly.

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

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ABOUT US

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.

For further information, please visit <u>www.auscann.com.au</u>

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