

AusCann to Accelerate Cannabinoid Drug Development Program for Human Registration

Key Highlights

- AusCann has engaged the CRO division of Cannvalate Pty Ltd to conduct a technical review on the Company's existing animal data and research assets for the development of cannabinoid-based drug candidates for human registration in the areas of traumatic injury and neurological disorders;
- The indications being explored by the Company have an initial addressable market of over US\$2B globally with a high likelihood of response to cannabinoid therapy;
- The CRO division of Cannvalate is a cannabinoid-focussed Contract Research Organisation with in-house clinical advisors and sub-consultants specialising in FDA and 505(b)2 registration pathways.

21st September 2021 - AusCann Group Holdings Limited (ASX:AC8) ('AusCann' or 'the Company') is pleased to announce that it has appointed Cannvalate Pty Ltd (Cannvalate) to complete a strategic review of AusCann's existing animal data and research assets to support the development of new cannabinoid-based drug candidates for human registration pathways.

Cannvalate is an Australian cannabis Company with three main divisions, including a full-service Clinical Research Organisation with in-house access to an established network of clinical trial research professionals including protocol designers, medical affairs, quality assurance, scientific affairs, biostatistics, data management, pharmacokinetics, project management, monitoring, safety and pharmacovigilance.

The scope of the assessment will address U.S FDA (Food and Drug Administration) regulatory pathways, commercial feasibility, clinical trial mapping and the pathology and symptoms for target indications with a high likelihood of response to cannabinoid therapy in the areas of traumatic injury and neurological disorders, with initial addressable markets of over US\$2B globally.

The technical assessment will also include a review of AusCann's CPAT-01 canine investigational formulation and existing animal safety, toxicology, pharmacokinetic and biomarker data which may be used to accelerate the development of a human cannabinoid-based drug candidate for FDA registration pathways.

ENDS

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 company focused on the development and commercialisation of cannabinoid-derived therapeutic products to address unmet needs for humans and animals within Australia and internationally. Our key difference is the commitment to rigorous product development, focused on providing reliable, stable and standardised cannabinoid-derived therapeutics products, whilst generating robust safety, quality assurance and efficacy data to support market access in various regulatory environments around the world.