AusCann
ASX RELEASE

AusCann Completes Successful Pre-Submission Meeting with the U.S FDA-CVM for CPAT-01

Key Highlights

- AusCann has held a positive Pre-Submission Meeting ('PSC') with the U.S FDA-CVM, to discuss the development and regulatory pathway for CPAT-01 in the United States.
- CPAT-01 is a cannabinoid-based veterinary medicine in development for FDA-CVM approval for the management of pain, inflammation and quality of life in dogs with osteoarthritis.
- The veterinary pain and inflammation market is worth over US$1b globally.
- The FDA-CVM has confirmed that the development program and strategy for CPAT-01 is consistent with its expectations and were highly engaged in the meeting.
- A Memorandum of Conference ('MOC') with formal guidance will be provided within 45 days, from which the Company is confident a predictable pathway to approval can be defined for CPAT-01.

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9 December 2021 - **AusCann Group Holdings Limited** (ASX:AC8) ('AusCann' or 'the Company') is pleased to announce that it has held its Pre-Submission Conference meeting ('PSC') with the U.S Food and Drug Administration, Centre for Veterinary Centre ('FDA-CVM') to discuss the development program and regulatory pathway for CPAT-01 in the United States.

The PSC meeting package was prepared with assistance from the Company's regulatory consultants and included an overview of the CPAT-01 program, with specific questions relating to the various technical sections required for a New Animal Drug Application ('NADA') to seek approval for CPAT-01.

The meeting was attended by representatives in various divisions from the FDA-CVM, including the Division of Companion Animal Drugs, Manufacturing Technologies, Toxicology, Environment, Clinical Pharmacology and Target Animal Safety.

The representatives from the FDA-CVM were highly engaged in the meeting and confirmed that the development program and manufacturing strategy for CPAT-01 is consistent with the agency's expectations. The agency provided advice for the Company's next phase of development and the same representatives will be evaluating the technical sections for CPAT-01 as they are submitted.

A Memorandum of Conference ('MOC') with formal guidance from the meeting will be provided within 45 days, and based on the feedback from the agency, the Company is confident that there is a predictable pathway to approval for CPAT-01.

AusCann has commenced the design phase for its Phase 2C clinical effectiveness trial and will use the formal feedback from the MOC to finalise its study plan. The purpose of the Phase 2C is to generate final pilot data to inform the design of the Company's Phase 3 pivotal program to support a NADA for the approval of CPAT-01, as a world "first-in-class" U.S FDA registered veterinary medicine.

Layton Mills, CEO of AusCann: *"We are delighted with the positive feedback, engagement and encouragement from the FDA-CVM at our PSC meeting, and are rapidly moving forward with our Phase 2C clinical program to support the registration of CPAT-01 in the U.S. The veterinary pain and inflammation market is worth over US$1b globally, and we believe a registered cannabinoid-based veterinary medicine in the U.S would have the potential to become a blockbuster animal health product."*

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.