AusCann
ASX RELEASE

AusCann Requests Formal Meeting with the FDA-CVM to Agree on the U.S Approval Pathway for CPAT-01

Key Highlights

- AusCann has submitted a pre-submission conference meeting request with the Food and Drug Administration, Centre for Veterinary Medicine ('FDA-CVM') for CPAT-01.
- CPAT-01 is a cannabinoid-based veterinary drug candidate in development for FDA-CVM approval for the management of pain, inflammation and decreased quality of life in dogs with osteoarthritis.
- The veterinary pain and inflammation market is worth over US$1b globally and there's an unmet need for safe and viable long term treatment options for dogs suffering from painful conditions.
- AusCann will share the Company's pre-clinical, Phase 1 and Pilot Phase 2 data at the meeting and will be able ask the CVM questions on the requirements for the overall development plan for the path to market in the USA.
- The PSC is the first formal meeting with the FDA-CVM for CPAT-01 and will determine the regulatory framework within which a predictable pathway to approval will be defined.

18th October 2021 - **AusCann Group Holdings Limited** (ASX:AC8) ('AusCann' or 'the Company') is pleased to announce that it has submitted a pre-submission conference meeting request ('PSC') with the Food and Drug Administration, Centre for Veterinary Medicine ('FDA-CVM') for CPAT-01, a Phase 2 veterinary drug candidate made from standardised THC (tetrahydrocannabinol) and CBD (cannabidiol) extracts, in development for pain, inflammation and decreased quality of life in dogs with Osteoarthritis.

In March 2020, CannPal opened an Investigational New Animal Drug file ('INAD') with the FDA-CVM for CPAT-01 following the submission of a summary of scientific rationale to the agency which included data generated from a robust pre-clinical and Phase 1 research program **[ASX:CP1 Announcement March 11, 2020].**

Since the opening of the INAD, the Company has engaged in regular meetings with its assigned Office of New Animal Drug Evaluations ('ONADE') project manager, to update the CVM on early progress in the Chemistry, Effectiveness and Safety technical areas of the CPAT-01 development program, ahead of the Company's first PSC meeting with the agency.

A pre-submission Conference meeting is an entitlement granted to drug sponsors under the Federal Food, Drug and Cosmetic Act in Section 512(b)(3) to discuss submission or investigational requirements, which include the number and types of studies or information that will be submitted to support the approval of a New Animal Drug Application ('NADA').

The outcome of the PSC will be a memorandum of conference, which is an official record received 45 days after the PSC with binding advice on the submission and general investigational requirements for a NADA for CPAT-01.

The veterinary pain and inflammation market is worth over US$1b globally and there's an unmet need for safe and viable long term treatment options for dogs suffering from painful conditions.

Layton Mills, Chief Executive Officer: *"This is a significant milestone for AusCann as we believe we are the first Company globally to request a PSC with the FDA for a cannabinoid-based veterinary drug candidate. AusCann has taken the global leadership position in animal health with its research, development and regulatory progress for CPAT-01 and we look forward to working with the FDA to determine the regulatory framework within which a predictable pathway to approval in the U.S can be defined."*

ENDS

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

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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.