

## **AusCann Receives U.S FDA-CVM Memorandum of Conference for CPAT-01**

### **Key Highlights**

- AusCann has received its official Memorandum of Conference ('MOC') from the U.S FDA-CVM, supporting the development and regulatory pathway for CPAT-01
- CPAT-01 is a cannabinoid-based veterinary medicine in development for FDA-CVM approval for the control of pain and inflammation in dogs with osteoarthritis
- The global veterinary pain management market is worth over US\$1b globally<sup>1</sup>
- The MOC is the official record from the Pre-Submission Conference meeting which was held virtually with the FDA-CVM in December 2021

---

**8 February 2022 - AusCann Group Holdings Limited** (ASX:AC8) ('AusCann' or 'the Company') is pleased to announce that it has received its official Memorandum of Conference ('MOC') from the U.S Food and Drug Administration, Centre for Veterinary Centre ('FDA-CVM'), providing formal guidance on the development program and regulatory pathway for the approval of CPAT-01 as a veterinary medicine in the United States.

The MOC is the CVM's official record of a successful Pre-Submission Conference meeting ('PSC') which was held virtually with the agency to discuss the ongoing development program for the approval of CPAT-01 as veterinary medicine for the management of pain, inflammation and quality of life in dogs with osteoarthritis [**ASX:AC8 December 9<sup>th</sup>, 2021**].

The PSC meeting package included an overview of the CPAT-01 program, with specific questions that related to the various technical sections that will be required for a New Animal Drug Application ('NADA') for the approval for CPAT-01 as a veterinary medicine in the United States.

The MOC provides the Company with clarity on an approval pathway for CPAT-01, including confirmation that AusCann will be able to progress its development program for the control of pain and inflammation in dogs with osteoarthritis as primary endpoints, with the potential to seek improvement in quality of life as a secondary endpoint.

The Company also received favourable recommendations relating to the Company's approach to a titration regimen for CPAT-01 to address the variability of cannabinoids, as well as confirmation that the Company's development plan for safety and toxicology will be sufficient, which greatly reduces the time and cost required for the program.

The global veterinary pain management market is projected to grow at a Compound Annual Growth Rate of 8% to reach US\$1.6b globally by 2023, and there remains a large unmet need for safe and natural treatment options for dogs suffering from painful conditions<sup>1</sup>.

AusCann has commenced the design phase for its Phase 2C clinical effectiveness trial 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.

**ENDS**

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

### **For more information, please contact:**

Layton Mills  
Chief Executive Officer  
info@auscann.com.au  
+61 8 6305 0705

Registered address: Level 5, 35 Havelock Street, West Perth WA 6005 Mailing address: PO Box 1746, Wangara WA 6947  
T: +61 6305 0705 E: [info@auscann.com.au](mailto:info@auscann.com.au) [www.auscann.com.au](http://www.auscann.com.au)

## 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.

1. Market and Markets, Veterinary Pain Management Market Report NSAID (Non-steroidal anti-inflammatory drug)