AusCann
ASX RELEASE

# AusCann Engages knoell Animal Health to Advance CPAT-01 U.S Program with the FDA-CVM

**Key Highlights**

- AusCann has engaged knoell Animal Health LLC to advise on the CPAT-01 clinical program and U.S regulatory strategy ahead of the Company's PSC meeting with the FDA-CVM;
- CPAT-01 is a Phase 2 standardised pharmaceutical veterinary drug candidate derived from THC and CBD extracts, in development for FDA-CVM approval for pain and inflammation in dogs;
- Dr Laura Treml is AusCann's technical lead for the engagement, bringing over 20 years of experience in companion animal practise and veterinary drug development for U.S and EU regulatory approvals;
- The veterinary pain and inflammation market is worth over US$1b globally and there's an unmet need for safe and viable treatment options for dogs suffering from painful conditions.

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**9th September 2021** - **AusCann Group Holdings Limited** (ASX:AC8) ('AusCann' or 'the Company') is pleased to announce that it has entered into an agreement with knoell Animal Health LLC (knoell) to be part of its clinical expert advisory group for the CPAT-01 development program and U.S regulatory strategy ahead of its Pre-Submission Conference meeting (PSC) with the Food and Drug Administration, Center for Veterinary Medicine (FDA-CVM).

Dr Laura Treml will be AusCann's technical manager for the project, bringing over 20 years of experience in companion animal practise and veterinary drug development with Companies such as Bayer and Aratana Therapeutics, including early stage development and late stage pivotal field studies for both the FDA-CVM and the United States Department of Agriculture, Center for Veterinary Biologics (USDA-CVB).

Dr Treml has managed a number of canine pain and anti-inflammatory development programs which has included the U.S FDA approval for Nocita (a long lasting analgesic for post-surgical pain in dogs), and the EU marketing authorisation for Galliprant (a market leading Nonsteroidal Anti-Inflammatory Drug for dogs with osteoarthritis).

The initial scope of work in the agreement includes;

- Participating in the Company's expert clinical advisory group to provide guidance for the design and technical requirements for a Phase 2C clinical effectiveness program for CPAT-01 in accordance with Veterinary Medicinal Products Good Clinical Practices (VICH GL9); and
- Providing consulting support for the regulatory strategy with the FDA-CVM ahead of the Company's PSC in accordance with the Code of Federal Regulations Title 21 and applicable FDA guidance for industry.

**Background and Phase 2C Timeline of Events**

In March 2020, CannPal opened an Investigational New Animal Drug (INAD) file with the FDA-CVM following the submission of a summary of scientific rationale with data generated from a robust pre-clinical and Phase 1 research program, including gene expression profiling, inflammatory biomarker data, and 2 pharmacokinetic studies with a total of 59 healthy beagles **[ASX:CP1 March 11, 2020].**

In April 2021, the Company updated the market on key clinical veterinary and owner scoring results from an 8-week, pilot Phase 2A clinical trial in 46 dogs with osteoarthritis, supporting the safe and effective use of the product for pain, lameness and quality of life **[ASX:AC8 April 30, 2021].**

The positive indicators of CPAT-01 improving pain, inflammation and mood based on the Phase 2A clinical and biochemical results were complemented by the promising safety profile confirmed in a 90 day pilot Phase 2B Target Animal Safety Study in 16 dogs **[ASX:CP1 October 29, 2020].**

Since the opening of the INAD, the Company has engaged in regular meetings with its assigned FDA-CVM Office of New Animal Drug Evaluation (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 a potential applicant under the Federal Food, Drug and Cosmetic Act in Section 512(b)(3). The purpose of the meeting is to discuss submission or investigational requirements with the FDA, which include the number and types of studies or information that will be submitted to support the approval of a new animal drug application.

The meeting will be used as an opportunity for AusCann to share the Company's Phase 1 and pilot Phase 2 data to receive formal guidance on the ongoing U.S development and regulatory plan for CPAT-01, with a Phase 2C clinical effectiveness study to commence upon receiving a Memorandum of Conference (MoC) from the FDA-CVM as a result of the meeting.

The Company remains on track to submit its meeting request in the current quarter and the PSC will be held up to 60 days after the request is submitted **(Figure 1)**.

***Figure 1. Anticipated Timeline of Events for Phase 2C Study***

| Milestone | Q3 2021 | Q4 2021 | Q1 2022 | Q2 2022 | Q3 2022 |
|---|---|---|---|---|---|
| Pre-Submission Conference (PSC) Request | Nearing completion | | | | |
| PSC Meeting | | Up to 60 days after the PSC request | | | |
| FDA-CVM Memorandum of Conference (MOC) | | Received 45 days after PSC with agreed U.S regulatory path | | | |
| Protocol Design and Ethics Approval | | Phase 2C protocol design and ethics submission | | | |
| Clinical Trial Sites and Manufacture of CTM | | Confirm clinical trial sites and prepare GMP clinical trial material | | | |
| Recruitment and Study Commencement | | | | Recruitment and live phase of study begins | |

Dr Laura Treml: *I'm delighted that AusCann are placing their confidence in knoell for this project. I know that the experience, capabilities and diligence of my team will enable us to provide the very best support. I look forward to working together towards approval in the USA, and hope AusCann's product will expand the treatment options for this debilitating condition in dogs.*

Dr Margaret Curtis, Chief Scientific Officer: *"It is exciting to have engaged Dr Laura Treml knowing the breadth of experience that she has in the research and regulatory space for canine osteoarthritis. I am looking forward to collaborating with knoell as we progress the development of CPAT-01 towards approval in the USA."*

**ENDS**

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

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**ABOUT KNOELL**

**knoell Animal Health LLC** ("knoell") is a USA-based consultancy company that brings together an exceptionally powerful team with expertise in all relevant technical areas and provides global product development and registration services to the animal health industry. The animal health team at knoell has technical staff based on three continents: North America, Europe, and Asia - the only knowledge-based animal health consultancy and clinical studies specialist benefitting from such a wide geographical spread.

**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.