AusCann
ASX RELEASE

CPAT-01 Improves Pain, Lameness and Quality of Life in Dogs with Osteoarthritis

Key Highlights

- AusCann has received the full analysis of clinical pain and lameness results for the Phase 2A Pilot study for CPAT-01, a cannabinoid-based veterinary medicine developed by CannPal Animal Therapeutics Ltd for pain and inflammation in dogs;
- The study was a world first, randomised, double-blind, placebo-controlled clinical trial in which client owned animals diagnosed with osteoarthritis were treated with Tetrahydrocannabinol (THC), combined with Cannabidiol (CBD) over an 8-week period;
- The positive indicators of CPAT-01 improving pain, lameness and mood based on clinical and biochemical results give the Company confidence moving forward with the development program;
- The Company has commenced drafting its PSC request (pre-submission conference) with the FDA/CVM (Food and Drug Administration, Center for Veterinary Medicine) to seek formal guidance on the CPAT-01 U.S development and regulatory plan;
- Attached is a link to a video presentation by Dr Margaret Curtis, Head of Research and Development at CannPal, providing an overview of CPAT-01 and the Pilot Phase 2A study results.

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30 April 2021 - **AusCann Group Holdings Limited** (ASX: AC8) ('AusCann' or 'the Company') is pleased to update the market on key clinical veterinary and owner scoring results for the CannPal CPAT-01 Pilot Phase 2A study supporting the safe and effective use of the product in dogs with osteoarthritis.

CPAT-01 is a standardised pharmaceutical product derived from natural THC and CBD extracts, formulated into a liquid oral solution to provide veterinarians with a safe and effective veterinary medicine for the treatment of pain and inflammation in dogs.

The veterinary pain and inflammation market is worth over US$1b globally and there is a need for viable treatment alternatives for dogs, particularly the elderly and compromised dogs where current treatments for pain and inflammation may be undesirable due to their potential negative side effect profiles or lack of effect.

A video presentation of the study results presented by Dr Margaret Curtis, can be viewed here: https://auscann.com.au/investors/cpat-01-phase2a-results-presentation/

Phase 2A Study Design

The study was a world first randomised, double blind, placebo-controlled dose ranging study, in which client owned dogs diagnosed with osteoarthritis were assigned to 1 of 4 treatment groups (Placebo, 0.27mg/kg, 0.54mg/kg and 0.9mg/kg cannabinoids) and dosed twice daily over a period of 8 weeks.

The study protocol included several subjective pain, mobility and quality of life (QOL) assessments as well as objective measures of a range of biomarkers and clinical safety outcomes.

The recruitment target for the trial was 60 dogs, however, substantial slowing in enrolment due to the impact of COVID-19, and the social distancing measures implemented in Australia, led CannPal to the decision to finish the study with 46 dogs having completed treatment.

Clinical Veterinary and Owner Assessment Models

Veterinarians completed a 5-part lameness assessment in conjunction with each physical examination of the dogs in the study at 0, 28 and 56 days. The Vet Lameness Scoring (VLS) included a review of clinical lameness, joint mobility, evenness of weight bearing, pain on palpation of the joint and an overall impression of the dog by the vet.

Scores were analysed separately and pooled together and change over time was assessed at 28 and 56 days with comparisons made between and within CPAT-01 treatment groups and placebo, as well as all CPAT-01 treatment groups combined.

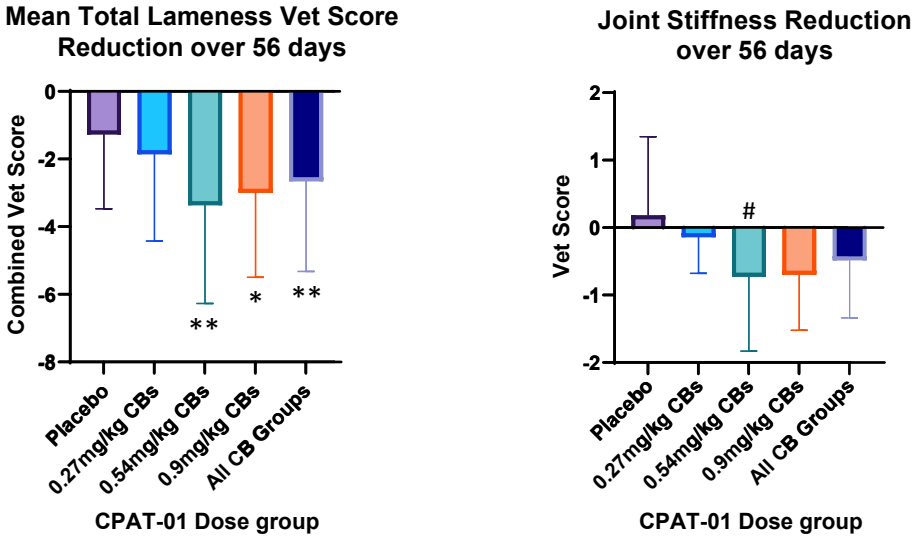
Owners also completed a number of pain and activity scoring assessments every 2 weeks during the treatment period, including the CBPI (Canine Brief Pain Inventory) the COI (Canine Orthopaedic Index) and the HAS (Hudson Activity Scale).

Scores were analysed separately and pooled together and change over time was assessed at 0, 14, 28, 42 and 56 days with comparisons made between treatment groups, all CPAT-01 treatment groups combined and placebo, as well as within groups.

Key Clinical Veterinary Scoring Results (VLS)

A total reduction in veterinary lameness scoring was observed in all dogs treated with CPAT-01, showing improvement over time which was numerically better for treated dogs compared with placebo. For within group analysis compared with baseline, there was a significant improvement for the highest CPAT-01 dose groups (P<0.1, P<0.05) and all CPAT-01 groups combined (P<0.05) over 56 days, which was not observed in the placebo group.

Placebo dogs had worse mobility after 56 days of treatment, whereas treated dogs had improved and this improvement was significant (P<0.1) for the middle CPAT-01 dose group. A test for dose trend in joint mobility was also significant which indicates that there was a positive dose response to CPAT-01 treatment for joint mobility.



***P<0.1, **P<0.05 = Compared with baseline, within groups comparison;**
#P<0.1 = Compared with baseline, between groups comparison

Key Clinical Owner Scoring Results (CBPI and COI)

The CBPI followed a similar outcome to the veterinary scoring with all groups showing improvement over time. While there was no significant difference between groups for CBPI, the within group analysis showed a significant reduction (P<0.1, P<0.05) in pain and interference associated with pain from baseline for all treatment groups over 56 days.

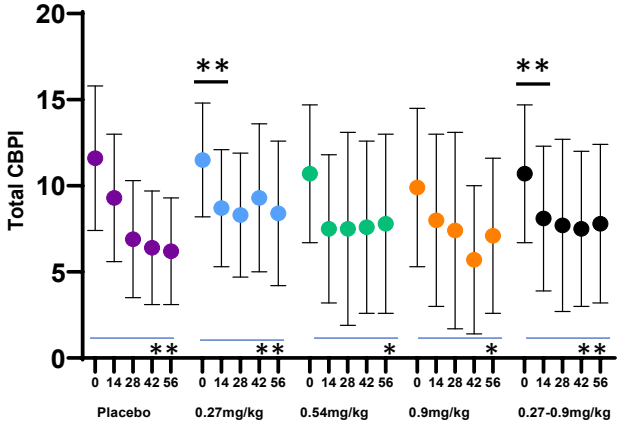
Considering the within group analyses, significant improvements (P<0.05) in the CBPI can also be seen in the first 14 days for the lowest CPAT-01 dose group and all CPAT-01 groups combined, while the placebo group change was not significant over that same 14-day period.

The highest CPAT-01 dose group numerically recorded the greatest reduction in CBPI on day 42 however the high variability within and between groups prevented this from reaching significance. A higher than expected placebo effect and the high variability of the responses in the survey meant that there was no significant separation between groups in the latter part of the study for CBPI.

As with the CBPI, all groups showed substantial improvements in the COI and were most noticeable in the first 14 days of treatment, where a significant improvement (P<0.05) in total COI scores for all CPAT-01 treatment groups combined and compared with baseline was observed, while over the same period no significant improvement in the placebo was seen.

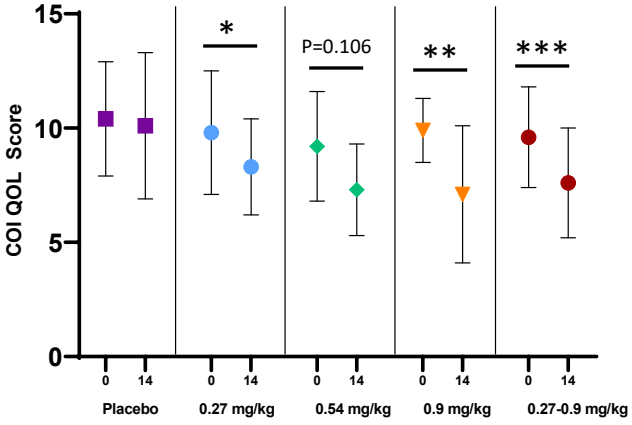
The Company was pleased to note that the Quality of Life (QOL) section of the COI scoring appeared to have the most marked effect, again most noticeably at day 14 day of treatment where all groups combined showed a statistically significant (P<0.01) improvement while statistical significance was not observed in the placebo group.

Total Canine Brief Pain Inventory (CBPI)
Scores by CPAT-01 Treatment group over 56 days



Mean CBPI with SD error bars
***P<0.1,**P<0.05 compared with day 0, within group comparison**

Quality of Life in Canine Orthopedic Index (COI)
Scores by CPAT-01 Treatment group over first 14 days



Mean CBPI with SD error bars
***P<0.1,**P<0.05 ***, P<0.01 compared with day 0, within group comparison**

Key Hudson Activity Scale Results (HAS)

HAS was another scale used to assess lameness in dogs by the owners. A series of questions on a visual analogue scale were converted to numbers by measurement along the scale and summed to give the total score.

A significant improvement in total HAS for all CPAT-01 treatments combined compared with baseline was observed at 14 days (P<0.1) and 28 days (P<0.01) while over the same periods no significant improvement in the placebo group was seen.

Daily Observation Logs (Summary Measures)

Owners also documented daily clinical observations of their dogs using diaries and free text. Summary measures were used to analyse the data, which are a method for analysing daily observational data vs. intermittent surveys which can miss the highs and lows that occur between assessments.

This is useful at providing a more comprehensive description of the dog's response to cannabinoid treatment seen by owners, compared with the intermittent owner surveys, to get a better understanding of true effect which could be masked by high placebo responses in subjective scoring.

The daily clinical observation diaries were converted to a score based on a set of rules relating to positive, negative or neutral comments on the dogs pain, mobility and happiness each day. A cumulative curve was created for each dog, and scores at day 14, 28, 42 and 56 were used as the summary measures and subsequently compared between treatments.

Consistently across all summary measures, the observations from the owners of CPAT-01 treated dogs had more positive comments reflecting improvements in pain, mobility and mood when compared with owners of placebo treated dogs which was consistent at 14, 28 and 56 days.

Key In-Vivo Biomarkers

In addition, ELISA biomarker testing was conducted on a subset of the plasma samples for 28 dogs that were moderately to severely affected with osteoarthritis prior to treatment and the results of this component of the study were released previously by CannPal **[CannPal ASX Announcement: Jan 6, 2020].**

The Company was pleased to see the clinical scoring announced today align with the positive benefits observed in the Key *In-Vivo* Biomarker Results, which are believed to be the first-time that mood modification has been chemically documented in dogs with osteoarthritis treated with concomitant THC and CBD.

Summary and Next Steps

We are pleased to report that the veterinary and owner scoring results from the Pilot Phase 2A Study, along with the key in-vivo biomarker results, support the use of CPAT-01 for pain, lameness and improved quality of life in client owned dogs diagnosed with osteoarthritis.

The positive indicators of CPAT-01 improving pain, inflammation and mood based on clinical and biochemical results, give the Company confidence moving forward with the development program for CPAT-01.

The data generated from this study will help inform the design of the Company's ongoing development program, and AusCann has re-commenced drafting a formal request for a PSC (pre-submission conference) with the FDA/CVM (Food and Drug Administration, Center for Veterinary Medicine).

The meeting will be used as an opportunity to share the Company's Phase 1 and Pilot Phase 2A data generated from this study and receive formal guidance on its ongoing U.S development and regulatory plan for CPAT-01.

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

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.