**12th December 2018 | CannPal Animal Therapeutics Limited ACN: 612 791 518 | ASX:CP1**

# *CannPal Successfully Completes Phase 1B Cannabinoid Study in Dogs*

## Key Highlights

- CannPal has successfully completed dosing the last treatment group for its Phase 1B Study for CPAT-01, in development as a pain and inflammatory control for dogs;
- 48 mixed beagles and foxhounds were recruited for the study across various age and weights, with no adverse events reported across all treatment groups;
- Gene expression study results so far have revealed clear cannabinoid impact in important pain and inflammatory pathways supporting the proposed pain and inflammatory control claims for CPAT-01;
- The Company has commenced its battery of regulatory required toxicology studies in the United States. The results of the first study are on track for confirming the toxicological safety of CPAT-01; and
- CannPal has received two ethics approvals to expand the testing of CPAT-01 in feline studies with over 20 cats recruited and two study sites confirmed.

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**12th December 2018:** Animal health company **CannPal Animal Therapeutics Limited (ASX:CP1)** ("CannPal" or "the Company") is pleased to announce that it has successfully completed dosing for its Phase 1B study for CPAT-01, being developed as a regulatory approved pain and inflammatory control for dogs.

In late 2017 the Company designed a robust Phase 1 study in two stages to determine the pharmacokinetic and underlying gene expression profile of CannPal's cannabinoid-derived formulations in the canine body.

CannPal successfully completed the first stage of this study in April 2018. 11 dogs were selected in Phase 1A with 8 receiving treatment and 3 placebo. The endpoints of the study were to confirm the safety of CannPal's formulations for CPAT-01 and collect pilot pharmacokinetic data for use in Phase 1B. No adverse events were reported in each treatment group and all observational and pharmacokinetic endpoints were met.

### *Phase 1B*

The Company is pleased to announce it has successfully finished the dosing and live phase observations for Phase 1B. Over 48 Beagle and Foxhounds were recruited for the second phase of the study across various weights and ages. The endpoints for this study included:

- Gain pivotal GLP (good laboratory practices) pharmacokinetic data to support regulatory submissions
- Get early indication of the dose range for Phase 2 pilot studies
- Confirm cannabinoid impact on identified gene expression targets seen in Phase 1A
- Identify tolerability at up to 5x estimated dose of THC and CBD

CannPal is pleased to report that no adverse events were reported in dogs across all treatment groups in Phase 1B.

Additionally, gene expression studies so far have revealed clear cannabinoid impact in important pain and inflammatory pathways supporting the proposed chronic pain control claims for the Company's proprietary formulation of CPAT-01.

CannPal is now working with a Melbourne based integrated medical laboratory to identify the drug's effects on key chemokine and cytokines that are associated with the activated pain and inflammatory genes highlighted in these Phase 1 studies. The results of this in conjunction with the gene expression data will support the dose justification for CPAT-01 prior to commencing the clinical program.

## Phase 1: Overview of Outcomes

- Gene expression studies revealed clear molecular profile signatures in important pain and inflammatory pathways supporting the proposed pain and inflammatory control claims for CPAT-01;
- New data was generated to support additional intellectual property claims;
- All formulations were well tolerated at 0.3, 1x and 5x dose;
- No adverse events were reported at the dosages administered; and
- Potential safe dose range with optimal pharmacokinetics has been identified and will be used for a pilot study in osteoarthritic dogs.

The Company has generated significant data on the pharmacokinetic and gene expression profiles of cannabinoids in dogs. This data will be used to commence the protocol development for the first Phase 2 study, a pilot dose determination study in client-owned animals with osteoarthritis to clinically validate the effects seen in Phase 1 studies.

The Company hopes to commence recruitment for this study in Q1 2019.

### *Regulatory*

The Company has commenced regulatory required toxicology studies in the United States, an essential component of the global regulatory submission data pack for CPAT-01. CannPal's US based research partner, BioReliance, received DEA approval to commence the Ames and Mouse Lymphoma studies as part of the Company's toxicology data pack, with the research being managed by CannPal's Toxicology Adviser, Dr Jeffery Sherman. The results of the first study are on track for confirming the toxicological safety of CPAT-01.

The results of the early toxicology studies along with the pharmacokinetic and safety data generated in Phase 1A and B will be filed following an INAD (Investigational New Animal Drug) application with the FDA (Food and Drug Administration) in early 2019 in preparation for a pre-submission meeting with the ONADE (Office of New Animal Drug Evaluation) group in CVM (FDA's Center for Veterinary Medicine).

CannPal was also granted an official sponsor fee waiver on 9th November 2018 from the FDA/CVM under the significant barrier to innovation provision of the FDA's Animal Drug User Fee Act (ADUFA) of 2003. The waiver covers the current and annual estimated USD $75,000 FY18 ADUFA sponsor fee that must be paid when a Company files an INAD. The program was established to benefit small R&D Companies developing new and novel drug candidates, of which CPAT-01 was included.

### *CPAT-01C Cat Study*

The Company is also pleased to announce it has received ethics approvals to commence the testing of its lead canine pain and inflammatory drug candidate, CPAT-01, in cats.

CannPal recently announced it had entered into a research agreement with a leading feline

veterinary research organisation to expand the CPAT-01 development program to include cats, a growing opportunity in the animal health market.

Cats represent over 25% of the companion animal drug market and there's a clear unmet need for safe therapeutics that can be used long term to treat pain and inflammation in felines. Over 20 cats have been recruited for the study across varying weights and ages.

The animal phase of the study was originally planned for Q4 2018, but is now expected to commence early in 2019 across multiple research sites.

***CannPal's Head of Research and Development, Dr Margaret Curtis:***

*"These are very promising results that have shown good absorption of our proprietary combination of plant derived cannabinoids in healthy dogs. These studies have also shown that gene regulation associated with pain and inflammatory pathways in these dogs was positively influenced by treatment. This gives us confidence in the effects of cannabinoids on key inflammatory markers associated with pain and arthritis. We are closely approaching readiness for submission of an INAD with the US-FDA and preparing for pilot clinical work to confirm the positive indications we have seen for CPAT-01 for the control of pain and inflammation in dogs with osteoarthritis.*

***CannPal's Founder and Managing Director Layton Mills:***

*"I am very pleased at the speed in which we are progressing through the CPAT-01 development plan, but more importantly, the significant amounts of data we are collecting along the way. Our vision is to be one of the first animal health Companies to provide veterinarians with GMP produced and regulatory approved cannabinoid-derived therapeutics for pets. We have been strict on resources and strong on creativity to ensure we remain well capitalized to continue with the development of CPAT-01 in 2019, which wouldn't be possible without the help and support of our experienced research partners."*

***About CannPal Animal Therapeutics***

CannPal Animal Therapeutics Limited (ASX: CP1) is a pharmaceutical-focused animal health Company researching the benefits of medical cannabis for companion animals. CannPal is researching and developing medicines derived from cannabinoids to provide veterinarians with clinically validated and standardised therapeutics to treat animals in a safe and ethical way.

CannPal has identified a significant opportunity to benefit from the rapidly growing medical cannabis and health markets by developing innovate therapeutics derived from the cannabis plant. The Company is working closely with regulatory authorities and veterinary research organisations conducting clinical trials to commercialise therapeutic products that will meet regulatory approval and support the health and well-being of companion animals. To learn more please visit: www.cannpal.com

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