

3rd Sep 2018 | CannPal Animal Therapeutics Limited ACN: 612 791 518 | ASX:CP1

CannPal Commences Phase 1B Study for Lead Drug Candidate CPAT-01D

Key Highlights

- Commenced Phase 1B of the Pharmacokinetic and Safety study for CPAT-01D, a cannabis-derived pain control for dogs
- Follows successful Phase 1A study which showed excellent safety and tolerability for CPAT-01D
- 48 Beagles and Foxhounds of both sexes in wide weight and age ranges have been enrolled after clinical screening and examination
- The live phase of the study is expected to be completed late in Q4 2018

3rd September 2018: Animal health company **CannPal Animal Therapeutics Limited (ASX:CP1)** ("CannPal" or "the Company") is pleased to announce that it has commenced Phase 1B of the Pharmacokinetic and Safety study for CPAT-01D, a cannabis-derived veterinary medicine being developed as a pain control in dogs.

Phase 1B is a continuation of the Pharmacokinetic and Safety Study which started earlier in 2018 and showed excellent safety and tolerability for CPAT-01 [ASX Announcement: June 18, 2018]. Phase 1B builds on the pilot data already generated, and includes additional endpoints.

After completing clinical screening and veterinary examinations, 48 dogs were enrolled for this study, including adult Beagles and Foxhounds of both sexes and over wide weight and age ranges. Phase 1B will proceed in two stages, with Beagles commencing dosing today (September 3rd 2018) and Foxhounds to follow in Q4 CY18.

Phase 1B: study design	Phase 1B: endpoints
<ul style="list-style-type: none">• Dose ranging + pharmacokinetic + safety study• 48 dogs (40 treated / 8 control)• 1 NSW purpose-built research site• Mixed beagles and foxhounds• Various weight, age, and sexes	<ul style="list-style-type: none">• Pivotal GLP pharmacokinetic data to support regulatory submissions.• Early indication of the dose range• Cannabinoid impact on identified gene expression targets• Tolerability at up to 5x estimated dose of THC and CBD

The study is designed to demonstrate cannabinoid pharmacology in dogs according to Good Laboratory Practice (GLP) as a first step in generating pivotal data for regulatory submissions. It will also provide an initial indication of the dose range and tolerability at five times the estimated dose, in preparation for future pivotal safety studies required by regulatory bodies.

As part of Phase 1B, the Company has also implemented advanced gene expression analysis using RT-PCR arrays customised for CannPal to examine the up-regulation or down-regulation of genes in known pain and inflammatory pathways specific to dogs. Over 350



genetic markers are being analysed before and after consumption of cannabinoids to further support the understanding of the mode of action and effects of cannabinoids on pain and inflammation.

This innovative approach in the pharmaceutical development of animal health products has potential to allow better understanding of the effects of cannabinoids in dogs in a shorter amount of time and with fewer animals.

With the results from these Phase 1A and B studies, the Company plans to prepare to file an Investigational New Animal Drug (INAD) application with the United States (US) Food and Drug Administration (FDA) and will begin designing the protocol for the Company's pilot dose determination study to commence in H1 CY19, which will include client-owned animals with osteoarthritis.

CannPal's Founder and Managing Director Layton Mills: "It is excellent to see the significant progress we are making with CPAT-01, and the quick turn-around time between Phase 1A and Phase 1B. CPAT-01 has the potential to offer a new solution for dogs that suffer from painful conditions and we look forward to rapidly progressing through Phase 2 of this exciting research, at the completion of our Phase 1 studies"

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 innovative 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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For further information, please contact:

CannPal

Layton Mills
Founder and Managing Director
M: +61 431 302 667
E: layton@cannpal.com

Media enquiries

Julia Maguire
The Capital Network
M: +61 419 815 386
E: julia@thecapitalnetwork.com.au



@CannPalAT



facebook.com/CannPal

