

24 September 2018 | CannPal Animal Therapeutics Limited ACN: 612 791 518 |
ASX:CP1

CannPal Granted FDA Sponsor Fee Waiver for Lead Drug Candidate

Key Highlights

- CannPal has been granted a US FDA (Food and Drug Administration) Sponsor Fee Waiver for CPAT-01 under the FDA's Animal Drug User Fee Act of 2003 (ADUFA)
- The ADUFA act allows the Food and Drug Administration to collect user fees for certain products, applications and drug sponsors
- The waiver applies to the FY 2018 ADUFA sponsor fee (currently USD \$75,150) to be paid every year while a drug sponsor has an application open with the FDA
- This is CannPal's 2nd fee waiver, having been granted a MUMS (Minor Use / Minor Species) Sponsor Fee Waiver for an osteosarcoma pain indication in 2017

24th September 2018: Animal health company **CannPal Animal Therapeutics Limited (ASX:CP1)** ("CannPal" or "the Company") is pleased to announce that it has been granted its second US FDA (Food and Drug Administration) Sponsor Fee Waiver for its lead drug candidate CPAT-01.

The waiver was granted under the significant barrier to innovation provision of the FDA's Animal Drug User Fee Act (ADUFA) of 2003, as codified at section 750(1)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for FY 2018.

The waiver covers the current USD \$75,150 FY18 ADUFA sponsor fee which can be renewed each US fiscal year. CannPal may also be eligible for reductions in other fees such as the drug application fee which can cost in excess of USD \$300k.

The Company was initially granted a fee waiver for an osteosarcoma pain treatment under the Minor Use/Minor Species (MUMS) pathway in 2017 which is a pathway that applies to diseases that affect a minor number of patients every year. This new waiver under the barrier to innovation pathway is applicable to much broader indications, which allows CannPal to apply the waiver to CPAT-01D, which is being developed as a pain control in dogs.

CannPal plans to take the results from the recently commenced Phase 1A and B studies to file an INAD (Investigational New Animal Drug) application with the FDA prior to the AU FY19 financial year, at which point the Sponsor fee would be required to be paid.

***CannPal's Founder and Managing Director Layton Mills:** "Receiving this fee waiver not only provides additional cost savings for the Company but also further validates our focus on following regulatory protocol and seeking added value opportunities for our shareholders. The Phase 1B study is now well underway and we are looking forward to continuing on our path of developing safe and scientifically-proven treatments for companion animals."*



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



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