11th March 2020 | CannPal Animal Therapeutics Limited | ASX: CP1
ASX ANNOUNCEMENT

FDA Establishes Investigational New Animal Drug (INAD) file for CPAT-01

Key Highlights

- The Food and Drug Administration, Center for Veterinary Medicine (FDA-CVM) has established an INAD for CannPal's lead cannabinoid-derived drug candidate, CPAT-01;
- The opening of the INAD file will be followed with a Pre-Submission Conference request with the FDA-CVM to discuss the overall regulatory pathway for CPAT-01;
- The INAD file is also a prerequisite for a Notice of Claimed Investigational Exemption (NCIE) which allows the shipping of investigational drug product to study investigators in the US;
- The Company has received an FY20 barrier to innovation fee waiver, which removes the annual Sponsor Fee required to be paid upon the opening of an INAD file.

11th March 2020: Animal health company **CannPal Animal Therapeutics Limited (ASX:CP1)** ("CannPal" or "the Company") is pleased to announce that the Food and Drug Administration, Centre for Veterinary Medicine (FDA-CVM) Office of New Animal Drug Evaluation (ONADE) has established an Investigational New Animal Drug (INAD) file for CannPal's lead cannabinoid-derived drug candidate, CPAT-01.

CPAT-01 is a highly purified pharmaceutical product derived from natural THC and CBD extracts which is being developed as a veterinary medicine for the reduction in symptoms associated with osteoarthritis, with an initial focus on pain and inflammation.

A summary of the scientific rationale for the development of CPAT-01, which included data generated from the pre-clinical and Phase 1 research program, was provided to the FDA with an INAD request on 14th January 2020.

Sponsors of new animal drugs typically submit a request to open an INAD file when they have enough pilot data to start discussing the development process with the FDA and/or they want to begin shipping drug for use in investigational studies in the US.

The INAD file contains correspondence and submissions that may be used to support a new animal drug application (NADA) for CPAT-01 and allows CannPal the ability to request a Pre-Submission Conference (PSC) with the FDA-CVM.

In the PSC, CannPal will propose its detailed development plan for CPAT-01 and discuss the overall regulatory pathway for the drug candidate. This meeting is expected to take place in Q2/Q3 2020.

The establishment of an INAD file also allows CannPal to submit a Notice of Claimed Investigational Exemption (NCIE) which allows the shipping of investigational drug product to study investigators in the US for future animal studies, including but not limited to, further pilot studies and pivotal studies for effectiveness and safety.

The Company is pleased to announce that it has also received a fee waiver granted under the significant barrier to innovation provision of the FDA's Animal Drug User Fee Act (ADUFA). The waiver applies to the current FY20 ADUFA sponsor fee of approximately AUD $220,000, which is an annual fee required to be paid by the sponsor of a new drug upon creation of the INAD file.

Under the provision, a waiver or reduction of certain sponsor fees is appropriate when the product for which the waiver is being requested is innovative, and the fee would be a significant barrier to the requestor's ability to develop, manufacture, or market the innovative product or technology.

The waiver provides significant financial benefit for the maintenance of CannPal's INAD, and must must be renewed yearly to maintain the reduction in fee's.

CannPal Managing Director, Layton Mills

"The establishment of our INAD file is a significant regulatory milestone for CannPal, and an important step on the pathway to the potential authorization of an animal health drug. We have made significant progress on the development of CPAT-01, and are excited to be able to discuss the regulatory pathway with the FDA-CVM at the upcoming Pre-Submission Conference".

About CannPal Animal Therapeutics

CannPal Animal Therapeutics Limited (ASX: CP1) is an animal health Company with a mission to provide pet owners and veterinarians with access to high quality, evidence based, plant derived therapeutic products to promote better health and well-being for animals.

Presently, the Company is focused on the development of pharmaceutical and nutraceutical products for dogs, for commercialisation in various markets around the world, using compounds derived from the hemp and cannabis plant.

To learn more please visit: www.cannpal.com

This announcement has been approved and authorised to be given to ASX by Mr Geoff Starr, the Chairman of CannPal Animal Therapeutics Limited.

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