



July 21st 2020 | CannPal Animal Therapeutics Limited | ASX: CP1
ASX ANNOUNCEMENT

DermaCann® Reduces Atopic Dermatitis Symptoms in Dogs

Key Highlights

- DermaCann® treatment substantially reduced CADESI-4 scoring in a clinical study for dogs with Atopic Dermatitis, by an average of 51% after 56 days of treatment;
- CADESI-4 (Canine Atopic Dermatitis Extent and Severity Index) is a gold standard method used to grade inflammation and skin lesions in dogs with Atopic Dermatitis;
- A positive impact on important skin inflammatory biomarkers in blood plasma was also observed in treated dogs between day 0 and 56;
- DermaCann® was well tolerated by all dogs on treatment, with no significant adverse events reported throughout the length of the 8-week study;
- The Company is now in discussions with animal health partners to advance the commercialisation of DermaCann® in various regulatory and non-regulatory markets.

July 21st 2020: Animal health company **CannPal Animal Therapeutics Limited (ASX:CP1)** (“CannPal” or “the Company”) is pleased to announce the completion of its safety and efficacy study for DermaCann®, an oral nutraceutical developed for healthy skin and immune function for dogs.

Treatment with 2 similar DermaCann® formulations resulted in a substantial improvement in CADESI-4 scores, with an average reduction of 51% for dogs on treatment, compared to a slight increase observed in the placebo group between days 0 and 56.

CADESI-4 (Canine Atopic Dermatitis Extent and Severity Index) is a gold standard method used to grade skin lesions in clinical trials to assess the impact of treatments in dogs with Atopic Dermatitis.

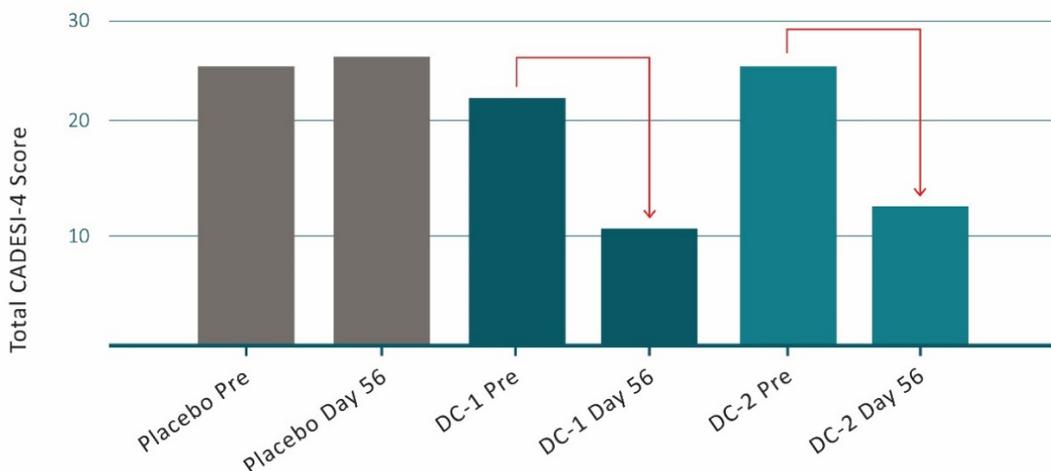


Fig 1: Mean of CADESI-4 scores in dogs treated with placebo or DermaCann® (DermaCann formulation 1 (DC-1) or DermaCann formulation 2 (DC-2)). Results from pre-treatment (day 0) to day 56. Lower score = treatment benefit.

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Dosing for the safety and efficacy study commenced in Q4 2019 with 30 dogs expected to participate in the trial, however due to the social distancing measures implemented by the Australian Government in response to COVID-19, CannPal made the decision to finalise the study with 13 dogs having successfully completed treatment.

Despite the reduced number of animals in this study, the differences between placebo and treatment indicate substantive and clinically relevant results.

Canine blood plasma samples were also taken from dogs at Day 0, Day 28 and Day 56 to assess the impact of treatment on various inflammatory and immune related biomarkers.

Ex-vivo biomarker analyses confirmed a reduction in multiple chemokines and cytokines associated with immune and inflammatory responses in dogs, when comparing blood samples taken from DermaCann® treated dogs with those on placebo. The most notable were Chemokine Ligand 1 (CXCL1) and Chemokine Ligand 2 (CCL2).

Both biomarkers are biologically relevant to the mode of action of effective treatments for Atopic Dermatitis in humans, supporting a potential mode of action for DermaCann® in dogs.

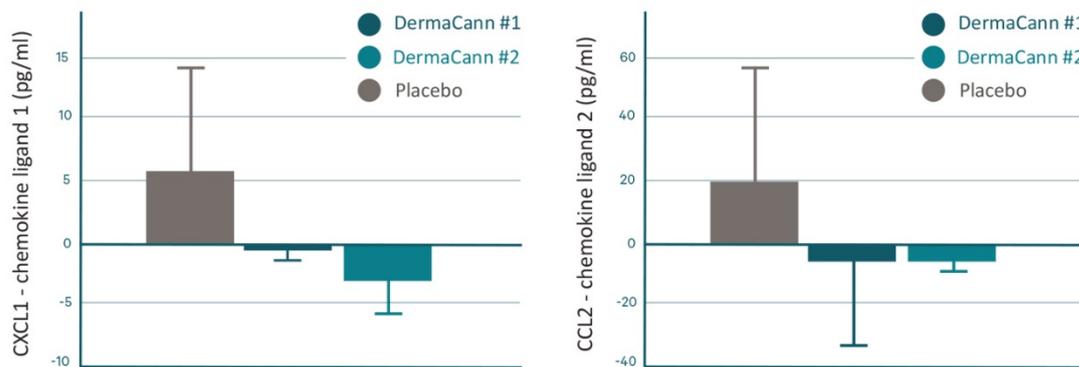


Fig 2: Changes in CXCL1 and CCL2 expression in dogs with Atopic Dermatitis after treatment with 2 different DermaCann® formulations, or placebo, as assessed by *ex-vivo* biomarker analyses in canine blood plasma samples.

Study design

The study design was a randomised, double-blind, placebo-controlled clinical trial to assess the safety and efficacy of two similar DermaCann® formulations in dogs with dermatological skin conditions, using different sources of cannabidiol extracted from the hemp plant. 8 dogs were allocated to the DermaCann® treatment groups, and 5 had been allocated to placebo.

Dogs were dosed twice daily over a period of 56 days, with veterinary and owner assessments conducted on all dogs on (or around) Day 0, Day 28 and day 56.

Clinical assessments were completed by Dermatology Specialist Veterinarians using the validated CADESI-4 model to assess skin lesions in multiple areas classically affected by canine Atopic Dermatitis. Assessments of skin and coat health were also completed by the Dermatologists and dog owners.

There were no significant adverse events reported throughout the trial and both DermaCann® formulations were well tolerated, with no dogs being withdrawn from the study.

CannPal will use the positive results from this trial as supportive efficacy data for the registration of DermaCann® in multiple markets as a nutraceutical for healthy skin and immune function for dogs.

The data has also been used to strengthen CannPals Intellectual Property portfolio, with the filing of the Company's second PCT international ("PCT") patent application. This application is expected to establish an exclusivity period for the Company's DermaCann® formulation extending to mid-2040.

The Company still intends on completing its Target Animal Safety study for DermaCann®, which is a regulatory requirement for the registration of the product in Australia and New Zealand and anticipates a commencement date for this trial in H2 2020.

CannPal has also advanced discussions with various animal health partners to progress the commercialisation of DermaCann® in markets that may not require product registration due to the relaxing of regulations for hemp-derived CBD.

CannPal Head of R&D, Dr Margaret Curtis

We're extremely pleased to see such positive results from this study, which will support our authorisations for DermaCann® in various markets. This data complements our solid product stability profile and user safety research, to provide veterinarians with a novel, data-supported robust product for healthy skin and immune function in dogs".

CannPal Managing Director, Layton Mills

"We have had DermaCann® in development for close to 3 years now, and the result of that work is a safe and differentiated CBD product for dogs with a compelling dataset and strong Intellectual Property. To our knowledge, this will be the only clinically validated oral CBD pet nutraceutical for skin health in dogs, and we look forward to furthering our commercialisation discussions for this exciting new product."

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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