AusCann
ASX RELEASE

AusCann Commences Australian Product Registration with First Regulatory Filing for DermaCann®

Key Highlights

- AusCann has submitted its first module to the Australian Pesticides and Veterinary Medicines Association (APVMA) to commence the submission of its dossier for the registration of DermaCann®, in development for anti-inflammatory and immune support in dogs with dermatological conditions;
- There are approximately 1 million dogs in Australia who suffer from dermatological conditions, and the global canine skin and dermatitis market is worth an estimated US$1.5B globally;
- Subject to approval, DermaCann® would be the first and only APVMA-approved, cannabinoid-based veterinary product to be legally supplied via prescription through Australian veterinarians;
- The DermaCann® submission in Australia compliments the previously announced submission for approval in South Africa and commercialisation plans for the United States where legislation in certain states permits the sale of animal health products containing CBD without registration.

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20 July 2021 - **AusCann Group Holdings Limited** (ASX:AC8) ('AusCann' or 'the Company') is pleased to announce that it has submitted its first module to the Australian Pesticides and Veterinary Medicines Association (APVMA) to commence the submission of its dossier for the registration of DermaCann®, in development for anti-inflammatory and immune support in dogs with dermatological conditions.

The Toxicology module was submitted following a positive response to a Pre-Application Assistance (PAA) request with the APVMA, outlining a project plan with agreed milestones for a time-shift application which allows for the staged submission of supporting data packages for longer module assessments (such as Toxicology) while other supporting data packages are being prepared for submission.

Subject to approval, DermaCann® will become a world 'first in class' regulatory approved oral cannabinoid-based veterinary product for skin health in dogs, and the first and only APVMA-approved medicine containing cannabinoids to be supplied via prescription through Australian veterinarians.

The Safety and Toxicological evaluation of DermaCann® was led by Dr Margaret Curtis, Head of Research and Development for AusCann, and Dr Jeffery Sherman, a Board-certified toxicologist who commenced consulting on the dossier in 2018. It includes almost 2,000 pages of supporting data and literature and is the result of over 3 years of research and dossier preparation including 8 independent *in-vitro* and *in-vivo* toxicology GLP (Good Laboratory Practises) studies completed across Hungary, Germany and the United States.

The global canine skin and dermatitis market is worth an estimated US$1.5B globally, and the approval of DermaCann® will provide veterinarians with a safe and clinically validated, cannabinoid-based veterinary product to be used as a beneficial therapy in a canine atopic dermatitis management regimen.

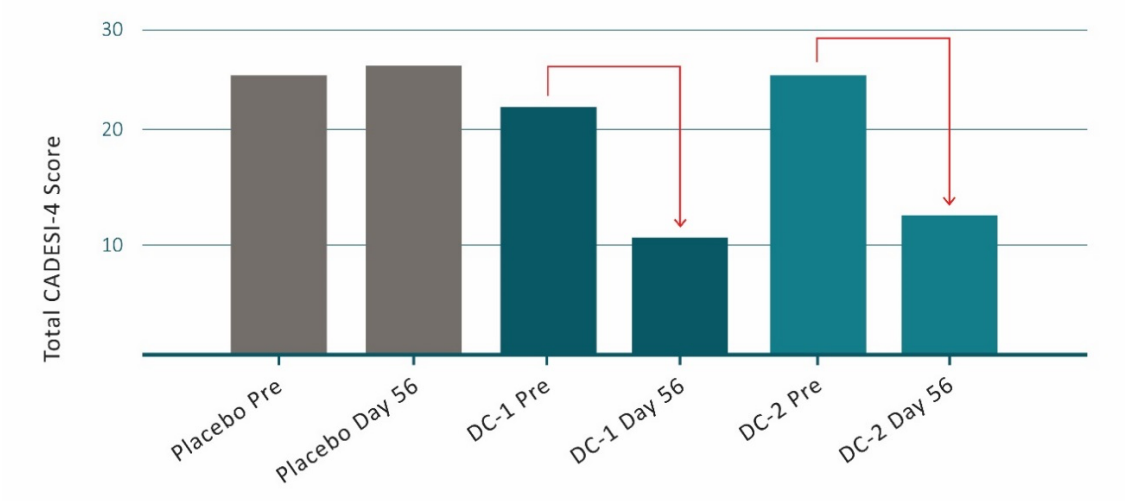
Reduction of Atopic Dermatitis Symptoms in Dogs

The unique property of DermaCann® is an exclusive combination of plant-based ingredients, including high-purity cannabidiol (CBD), to help strengthen the natural immune and inflammatory responses in dogs through activation of the endocannabinoid system.

In a randomised, placebo-controlled, double-blind study, DermaCann® was shown to be safe and effective at reducing inflammatory skin lesions in dogs diagnosed with atopic dermatitis **[ASX:CP1 Announcement - Jul 21, 2020]**.

Treatment with DermaCann® 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 **(Fig 1)**. CADESI-4 (Canine Atopic Dermatitis Extent and Severity Index) is a gold standard method used 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.



AusCann is currently undertaking further studies including a 90-day Target Animal Safety in the U.S, and *ex-vivo* biomarker research with the University of Melbourne to provide supportive data on the anti-inflammatory mechanism of action for DermaCann®, to add to the product's growing body of evidence **[ASX:CP1 Announcement - Oct 29, 2020]**.

Looking Forward

The Toxicology data pack is the first of 4 regulatory modules required for this application and will be followed by the submission of additional modules to the APVMA including safety, efficacy and manufacturing, which are in the final stages of completion. To grant a registration of a product, the agency must be satisfied that the safety, trade and efficacy criteria relevant to the product are met.

The full assessment by the APVMA is expected to take 18 months to complete, with an agreed target registration date of Q4 2022, pending the data provided meets the required criteria for approval.

The first regulatory filing for DermaCann® in Australia compliments the previously announced submission for regulatory approval with the South African Department of Agriculture, Forestry and Fisheries, and will be followed by a submission in New Zealand with the ACVM (Agricultural compounds and veterinary medicines).

The Company has also progressed preparations for the commercialisation of DermaCann® in the United States, where legislation in certain States permits the sale of animal health products containing CBD without registration.

Dr Jeffery Sherman, Safety and Toxicology Adviser: *"It's been very exciting to work on the dossier for the first veterinary product to contain CBD for regulatory approval in Australia. Now that the required safety studies and toxicological evaluation has been conducted, we can give greater certainty to veterinarians that this CBD medicine will be safe for use in dogs."*

Dr Margaret Curtis, Head of Research and Development of AusCann: *"We are pleased to have achieved this significant milestone with the submission of our first technical section for the approval of DermaCann®. We have engaged with the APVMA since March 2018, with valuable guidance resulting in what we believe to be a robust regulatory and project plan for our dossier submission."*

Layton Mills, CEO of AusCann: *"Commencing the formal registration pathway with APVMA is consistent with AusCann's objective of bringing safe, clinically developed and tested medicines for human and animal health to meet patients unmet health needs. We look forward to bringing this world-first product to veterinarians in Australia and other global markets."*

ENDS

This ASX announcement was authorised for release by the Board of AusCann.

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ABOUT AUSCANN

AusCann Group Holdings Limited (ASX:AC8) is an Australian-based company focused on the development and commercialisation of cannabinoid-derived therapeutic products to address unmet needs for humans and animals within Australia and internationally. Our key difference is the commitment to rigorous product development, focused on providing reliable, stable and standardised cannabinoid-derived therapeutics products, whilst generating robust safety, quality assurance and efficacy data to support market access in various regulatory environments around the world.