

AusCann Completes Submission for DermaCann® Registration in Australia and Advances U.S Launch

Key Highlights

- AusCann has submitted its last regulatory modules to the APVMA to support the registration of DermaCann® for anti-inflammatory and immune support in dogs with dermatological conditions.
- The global canine skin and dermatitis market is worth an estimated US\$1.5B globally.
- Subject to APVMA approval, DermaCann® will be the first regulatory-approved medicine containing cannabinoids to be legally available for prescription through veterinarians in Australia.
- The Company is progressing its U.S commercialisation plans with the launch of DermaCann® at VMX, the industry's largest trade show in the U.S, commencing in January 2022.

15 December 2021 - AusCann Group Holdings Limited (ASX:AC8) ('AusCann' or 'the Company') is pleased to announce that it has submitted its final regulatory data modules to the Australian Pesticides and Veterinary Medicines Authority ('APVMA') to complete the submission of its dossier for the registration of DermaCann® as an approved veterinary medicine for anti-inflammatory and immune support in dogs with dermatological conditions.

The Environment, Safety and Efficacy regulatory modules were submitted with supporting documentation that has been generated by the Company in the last 3 years of development. This complements the submission of the Toxicology and Chemistry regulatory modules previously announced to market.

The data in the final regulatory filings include;

- A randomised placebo-controlled double-blind study in client owned dogs with atopic dermatitis, which demonstrated a significant reduction in CADESI-4 scores (veterinarian scored, multi point skin damage and redness assessments) and inflammatory biomarkers, in dogs treated with DermaCann compared with placebo **[ASX:CP1 Announcement July 21, 2020]**;
- A randomised controlled Target Animal Safety Study in healthy colony-housed beagles conducted by Summit Ridge Farms, Pennsylvania, confirming DermaCann® to be safe for use at 1x, 3x and 5x the planned therapeutic dose **[ASX:AC8 Announcement October 13, 2021]**;
- Safety and efficacy data on the use of all proprietary ingredients used in DermaCann to provide strong literature-based support for the use of DermaCann® as a complementary therapy in the management of dermatological condition in dogs.

The overall dossier in which these modules form the final components is in the process of being reviewed under an APVMA agreed time shift application plan **[ASX:AC8 Announcement July 20, 2021]**.

Completion of the review of all modules is anticipated at the end of September 2022.

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 regulatory-approved medicine containing cannabinoids to be legally available for prescription through veterinarians in Australia.

DermaCann® U.S Launch at VMX Trade Show

The Company is pleased to announce that it is advancing its U.S commercialisation plans with the launch of DermaCann® at the industry's largest global trade show, the annual VMX Conference, at the Orange County Convention Centre in Florida U.S, commencing on January 15th 2022.

VMX is one of the world's leading veterinary conferences, attracting tens of thousands of veterinarians from across North America, and is used as a platform to promote new animal health products to distributors, animal health partners, and veterinarians from around the world.

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The global canine skin and dermatitis market is worth over US\$1.5b globally¹, and the launch 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.



Layton Mills, CEO of AusCann: *"Completing our final DermaCann® regulatory submissions is the culmination of over 3 years of hard work and is a pivotal milestone for AusCann. DermaCann® is on track to become the world's first regulatory-approved veterinary medicine containing cannabinoids to be legally available for supply via prescription through veterinarians. We look forward to introducing this world-first product to veterinarians in Australia and other global markets, starting with the United States at the upcoming VMX convention next month."*

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.

1. AusCann analysis based on Vetnosis, AnimalPharm, and other public and proprietary data sources