AusCann
ASX RELEASE

AusCann Completes High Dose Tolerance Study in USA and Advances DermaCann® Product Registration Plans

Key Highlights

- AusCann has completed a 90-day Target Animal Safety Study for DermaCann® in the U.S, confirming the product to be safe and well tolerated in dogs at up to 5 times the planned dose.
- DermaCann® is a clinically validated veterinary medicine, containing cannabidiol, in development for anti-inflammatory and immune support in dogs with dermatological conditions.
- The global canine skin and dermatitis market is worth over US$1.5b globally.
- The second data module to support the registration of DermaCann® in Australia has now been submitted with the Australian Pesticides and Veterinary Medicines Association.
- AusCann has commenced the registration process for the New Zealand Authorisation of DermaCann® as an Agricultural Compounds and Veterinary Medicine.

---

13 October 2021 - **AusCann Group Holdings Limited** (ASX:AC8) ('AusCann' or 'the Company') is pleased to announce that it has completed a 90-day Target Animal Safety study (TAS) for DermaCann®, confirming the product to be safe and well tolerated for use in dogs at up to 5 times the current planned dose. The TAS study is a requirement for the DermaCann® regulatory submissions in Australia and New Zealand.

Subject to approval, DermaCann® would be the first and only registered, cannabinoid-based veterinary product to be legally supplied via prescription through Australian and New Zealand veterinarians.

The safety study was completed at a veterinary research site in the United States and 15 healthy beagles were randomised into three groups for the trial (5 dogs per group);

1. Group 1 - control dogs - received no treatment
2. Group 2 - 3 X dogs - received 3X the recommended daily dose (3 mg/kg) of DermaCann®; and
3. Group 3 - 5 X dogs - received 5X the recommended daily dose (5 mg/kg) of DermaCann®

Dogs treated with DermaCann for 92 days at 3X and 5X the planned upper dose rate were clinically well tolerated with no clinically relevant nor statistical differences between treated and control dogs identified for all physical examinations, clinical observations, haematology and food/water consumption parameters.

Haematological parameters for all dogs remained within normal ranges with no difference compared to untreated dogs. Serum chemistry was also largely unimpacted by treatment. A mild increase in alkaline phosphatase (ALP) was observed with the 3X and 5X DermaCann® treatments compared to placebo which is a well-documented response to CBD in humans and animals.

All other clinical chemistry results were normal, supporting DermaCann® to be safe and effective product for use in dogs at up to 5X the planned dose.

Second Data Module Submission with the APVMA

The Company is pleased to announce that is has submitted its second data module to support the registration of DermaCann® with the Australian Pesticides and Veterinary Medicines Association ('APVMA'), following the commencement of the first data module submission in July 2021 under a time-shift application process **[ASX:CP1 Announcement July 21, 2020].**

The Chemistry, Manufacturing and Controls ('CMC') data submission included extensive data to support the registration of cannabidiol as a "new active constituent" along with data to support the quality of DermanCann® as a final product. This data module allows an in-depth assessment of the manufacturing process, quality controls, product specifications, analytical methods, and product stability, consistent

with VICH (Veterinary International Conference on Harmonization) guidelines for veterinary products and according to current good manufacturing practices (cGMPs). The two Phases of the CMC submission along with the Toxicology Submission for DermaCann® are now complete.

AusCann will submit its final data modules, being Efficacy and Safety and Environment, to the APVMA upon receipt of the final report for the Target Animal Safety Study (TAS) which is expected in Q4 2021.

Commencement of New Zealand Product Registration

AusCann is pleased to advise that it has appointed Intuit Regulatory Ltd, a Ministry of Primary Industries ('MPI') approved data assessor, to complete a Data Assessment Report for the New Zealand Authorisation of DermaCann® as an Agricultural Compounds and Veterinary Medicine ('ACVM').

Prior to the authorisation to import, manufacture, sell, or use an ACVM in New Zealand, it must be authorised with the Ministry of Primary Industries. The MPI requires an independent data assessment to be completed as a first step before an application for registration is made under the ACVM Act 1997.

Dr Julia McNab of Intuit Regulatory Ltd, is an ACVM-registered Independent Data Assessor and has been appointed to assess all aspects of the veterinary medicine data package for the New Zealand Authorisation of DermaCann®, including Chemistry and Manufacturing, Safety and Efficacy. An Environmental Protection Authority (EPA) assessment DermaCann is also being prepared.

DermaCann® has been in development for over 3 years and the commencement of registration for the product in New Zealand complements the previously announced submissions for approval in Australia and South Africa. The canine skin and dermatitis market is worth over US$1.5b globally, and there's an estimated 1.5m dogs across the SANZA region (South Africa, Australian and New Zealand) who suffer from dermatological conditions. First product registrations across SANZA are expected in late 2022.

Commercialisation plans for DermaCann® are also well advanced for the United States where legislation in certain states permits the sale of animal health products containing CBD without registration.

There are an estimated 15m dogs in the U.S who suffer from dermatological conditions, and the Company anticipates commercialisation activities to commence for DermaCann® in the United States in early 2022.

ENDS

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

For more information, please contact:

Layton Mills
Chief Executive Officer
info@auscann.com.au
+61 8 6305 0705

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.