

AusCann to Commence Exploratory Cannabinoid Trial in People with Spinal Cord Injury

Key Highlights

- AusCann has commenced the design phase for a clinical discovery trial to evaluate cannabinoids in people suffering from the symptoms associated with Spinal Cord Injury ("SCI")
- The global market for treatments associated with SCI is estimated at over \$US6B¹, and cannabinoids have been shown to be beneficial for symptoms such as spasticity, sleeplessness, pain and anxiety²
- This new exploratory trial follows the completion of a technical assessment led by the Clinical Research division of Cannvalate, for the use of cannabinoids for symptoms associated with SCI
- AusCann's medical advisory Board, led by renowned pain specialist Dr Marc Russo, will play a key role in shaping the design of the trial, with the design phase expected to be completed in early 2022

12th November 2021 - AusCann Group Holdings Limited (ASX:AC8) ('AusCann' or 'the Company') is pleased to announce that it has commenced the design phase for a clinical discovery trial to evaluate the Company's proprietary cannabinoid-based formulations in people with Spinal Cord Injury ("SCI").

The program follows the completion of a technical assessment completed by the Clinical Research division of Cannvalate Pty Ltd ("Cannvalate") for the use of CBD:THC for symptoms associated with SCI.

In September 2021, AusCann announced it had appointed the Clinical Research division of Cannvalate, to complete a strategic review of AusCann's existing animal data and research assets to support the development of new cannabinoid-based drug candidates which could be fast tracked for human registration pathways [**ASX:AC8 Announcement September 21, 2021**].

The scope of the assessment addressed U.S FDA (Food and Drug Administration) regulatory pathways, commercial feasibility, clinical trial mapping and the pathology and symptoms of people suffering from Spinal Cord Injury, which is an underdeveloped area with an addressable market size of US\$6B¹.

Following the completion of the assessment, AusCann has made the decision to withdraw from its previously planned investigator-led trial to redirect its resources to a research and development program which is better designed to support product registrations in targeted medical conditions.

The aim of this discovery program is to generate clinical data on the benefits of the Company's proprietary cannabinoid-based formulations for people suffering from symptoms associated with Spinal Cord Injury, which may then be used to support a more extensive human drug development program for marketing approval via the U.S Food and Drug Administration.

The Company's key medical advisors have seen encouraging benefits in patients with Spinal Cord Injury after the use of the Company's Neuvis® THC/CBD oral capsule's and will play a key role in shaping the design of the discovery program.

The initial study will commence upon approval by a human research ethics committee ("HREC"), with an initial HREC submission expected to be made in early 2022.

ENDS

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

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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.

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1. <https://www.globenewswire.com/news-release/2020/12/29/2151174/0/en/Global-Spinal-Cord-Trauma-Treatment-Industry.html>
 2. Stillman M, Capron M, Mallow M, Ransom T, Gustafson K, Bell A, Graves D. Utilization of medicinal cannabis for pain by individuals with spinal cord injury. *Spinal Cord Series and Cases*. 2019 Jul 10;5(1):1-8.