

15 August 2022
ASX Code: MXC
LSE Code: MXC

Results from Double-Blind, Randomised, Placebo Controlled Clinical Study of CannEpil[®] on driving performance

Key Highlights:

- Clinical Study undertaken by the Swinburne University of Technology, into the effect of MGC Pharma's Epilepsy treatment, **CannEpil[®]**, on driving performance, has been completed.
- Study results show that **CannEpil[®]** was found to be safe for post-treatment driving activities.
- The Clinical Study included the use of a driving simulator, a technique used to collect data required for the drug labelling when pre and early clinical studies indicate that a drug may cause somnolence or impair cognition.
- The results of the Study will be used to support safety data from future clinical trials when preparing submission packages for regulatory agencies (EMA and FDA).

MGC Pharmaceuticals Ltd (ASX, LSE: MXC, 'MGC Pharma' or 'the Company'), a European based bio-pharma company specialising in the production and development of phytomedicines, is pleased to provide the following results from a recently completed Randomised, Double Blind, Placebo controlled study investigating the effect of MGC's Pharma's Epilepsy treatment, **CannEpil[®]**, on vehicle driving performance, sedation and mood (**Trial**).

CannEpil[®]'s formulation is designed to treat Drug Resistant Epilepsy with a high CBD, low THC formulation which incorporates Graft Polymer's GraftBio[™] self-nanoemulsifying drug delivery system.

The Trial, sponsored by Cannvalate Australia, was undertaken by the Centre of Human Psychopharmacology at Swinburne University of Technology in Australia, under the auspices of the Medical Cannabis Research Collaboration.

With the increased use of medicinal cannabis globally, the Study was designed to assess the impact of a 1mL dose of 20:1 cannabidiol (**CBD**) to delta 9-tetrahydrocannabinol (**THC**) on driving performance, sedation and mood.

Recreational cannabis consumption is implicated in as many as 13% of drivers involved in fatal road traffic accidents in Australia, yet the direct effect of medicinal cannabis use on driving performance remains unclear. Legislative changes in Australia permit the regulated consumption of cannabinoid-based products for therapeutic purposes, however, currently there is no standard clinical or legal guidance outlining when it is safe to drive after its use, and a positive roadside saliva test for THC may lead to criminal convictions irrespective of prescribed use. It is hoped that standardised assessment of performance decrements, such of the findings of this Trial, will inform policy guidelines concerning responsible use of medicinal cannabis products.

Under approval from the Swinburne University Human Research Ethics Committee, the Trial assessed 31 healthy, fully licensed drivers (15 male, 16 female) aged between 21 and 58 years (with a median age of 36 years of age). Participants consumed either **CannEpil[®]** or a placebo, and at 90 minutes post treatment, completed a 40 minute "highway" drive using a driving simulator which was used to assess performance outcomes of deviation of lateral position, standard deviation of speed, and steering variability. Mood states and sedation levels were assessed by the Bond-Lader Visual Analogue Scale and Profile of Mood States which were administered prior to and/or following the driving task.

Results:

- Oral doses of 20:1 CBD to Δ 9-THC did not impair overall vehicle weaving, standard deviation of lateral position (SDLP) was not significantly altered in those administered CannEpil compared with placebo across the full drive.
- Standard deviation of speed (SDS) was not increased within 20 minutes' drive.

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- Sedation was not significantly increased during testing following CannEpil administration, however onset of increased sedation was reported by several participants between three to six hours after CannEpil was administered.
- The ‘contentedness’, measured by the Bond-Lader Visual Analogue Scale and Profile of Mood States was significantly increased following the driving task with those patients administered CannEpil.

CannEpil®

The **CannEpil®** formulation is designed to treat Drug Resistant Epilepsy with a high CBD, low THC formulation and incorporates Graft Polymer's GraftBio™ self-nanoemulsifying drug delivery system.

Epilepsy is one of the most common, serious neurological conditions, with approximately 33% of adults, and 20-25% of children with Epilepsy, suffering from Refractory Epilepsy (or Drug Resistant Epilepsy) which cannot be controlled with traditional anti-seizure medication¹.

In 2019 **CannEpil®** was made available for distribution and prescription in Ireland under full governmental health insurance coverage, making it the second product available with coverage in the Republic of Ireland as part of Ireland's Medical Cannabis Access Programme. There are over 37,000 people living with Epilepsy in Ireland alone, with **CannEpil®** providing a solution to a significant number of those cases². Between 300 - 400 patients have been prescribed **CannEpil®** across Australia and the Republic of Ireland monthly over the past two years.

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About MGC Pharma

MGC Pharmaceuticals Ltd (LSE: MXC, ASX: MXC) is a European based bio-pharma company developing and supplying affordable standardised phytomedicines to patients globally. The Company's founders were key figures in the global medical cannabis industry and the core business strategy is to develop and supply high quality phytocannabinoid derived medicines for the growing demand in the medical markets in Europe, North America and Australasia. MGC Pharma has a robust product offering targeting two widespread medical conditions – epilepsy and dementia – and has further products in the development pipeline.

Employing its ‘Nature to Medicine’ strategy, MGC Pharma has partnered with renowned institutions and academia to optimise cultivation and the development of targeted phytocannabinoid derived medicines products prior to production in the Company's EU-GMP Certified manufacturing facility.

MGC Pharma has a number of research collaborations with world renowned academic institutions, and including recent research highlighting the positive impact of using specific phytocannabinoid formulations developed by MGC Pharma in the treatment of glioblastoma, the most aggressive and so far therapeutically resistant primary brain tumour.

MGC Pharma has a growing patient base in Australia, the UK, Brazil and Ireland and has a global distribution footprint via an extensive network of commercial partners meaning that it is poised to supply the global market.

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¹ <https://www.epilepsy.org.uk/info/what-is-epilepsy>

² <https://www.epilepsy.com/learn/drug-resistant-epilepsy>