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Patent granted for CannEpil[®] Drug Delivery System by European IP Office

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Key Highlights:

- Patent granted by the Slovenian Intellectual Property Office for CannEpil[®] drug delivery carrier of self-nanoemulsifying drug delivery system (SNEDDS) in Ionic Complex Concentrate (CannEpil[®]-IL) for MGC Pharma’s phytocannabinoid-derived Investigational Medicinal Product drug, which is designed to treat drug-resistant (refractory) epilepsy with a high CBD, low THC formula.
- CannEpil[®] is one of four products approved for prescription under the Medical Cannabis Access Programme by the Health Product Regulatory Authority in the Republic of Ireland.
- Between 300 - 400 patients have been prescribed CannEpil[®] across Australia and Ireland on a monthly basis for the past two years.
- MGC Pharma have signed an agreement with leading specialty pharmacy supplier, Sciencus Rare, for the distribution of CannEpil[®] and neurological treatment CogniCann[®].
- CannEpil[®]-IL Patent utilises Graft Polymer's proprietary GraftBio[™] SNEDDS technology (Self-Nano Emulsifying Drug Delivery System), a unique platform designed to deliver active ingredients more effectively and in higher concentrations to cells, improving the bioavailability and synergy of the natural active ingredients.

MGC Pharmaceuticals Ltd (‘MGC Pharma’ or ‘the Company’), a European based bio-pharma company specialising in the production and development of phytomedicines is pleased to announce that the Slovenian Intellectual Product Office has granted a patent for the Company’s Drug Delivery System of self-nanoemulsifying drug delivery system (SNEDDS) in Ionic Complex Concentrate (CannEpil[®]-IL).

The Patent

The Patent sets out the formulation of the Self-nanoemulsifying Cannabinoids-Ionic Complex concentrate drug delivery system, the method of manufacture, and its capacity for enhancing stability, solubility, and bioavailability of drugs designed for multiple neurological therapeutic applications.

The SNEDDS is based on the IV type (oil-free) nanotechnology which guarantees a globular molecule size below 50 nanometres (nm), in order to pass through the Blood Brain Barrier. For the effective treatment of neurological diseases, molecules must be less than 25nm, therefore the Self-nanoemulsifying Cannabinoids-Ionic Complex concentrate is based on an “Ionic Complex” that greatly increases solubility and bioavailability of the Active Pharmaceutical Ingredient, reducing the diameter of the molecule.

The grant of the Patent provides MGC Pharma commercial protection over the intellectual property associated with **CannEpil[®]-IL**, including its unique formulation and manufacturing process for 20 years.

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.

CannEpil®

CannEpil® is designed to treat one of the most common serious neurological conditions, Epilepsy, which affects approximately 600,000 people in the UK, and ~50 million people worldwide,¹ with approximately 33% of those adults, and 20-25% of those children, suffering from Refractory Epilepsy (or Drug Resistant Epilepsy) which cannot be controlled with traditional anti-seizure medication.² The annual cost for patients with epilepsy in the United States is estimated to be approximately 12.5 billion dollars.³

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 cases.⁴ Between 300 - 400 patients have been prescribed **CannEpil®** across Australia and the Republic of Ireland monthly over the past two years.

CannEpil® is currently undergoing a randomised controlled trial investigating the effect of high CBD/low THC on driving performance, sedation and mood, in partnership with the Swinburne University of Technology in Australia (SUT). In addition to this, MGC Pharma are awaiting the approval of the import permits for **CannEpil®** by the Israel Ministry of Health in order to commence the Phase IIb trials for the formulation, as the Company looks to achieve Central Market Authorisation in the next 2-3 years.

Sciencus Rare Distribution

MGC Pharma has signed an agreement with leading European pharmacy supplier, Sciencus Rare for the distribution of MGC Pharma's **CannEpil®** and **CogniCann®** products (announced 5th April 2022). With a turnover of £1.9 billion, Sciencus Rare is the largest distributor of specialised healthcare solutions for patients with long-term conditions, rare and ultra-rare diseases, spanning 50 different products and partnered with 40 pharmaceutical companies to deliver over 1.2 million orders around the world.

Roby Zomer, Co-founder and Managing Director of MGC Pharma, commented: *"We are very pleased that the Patent for our proprietary drug delivery system has now been granted by the Slovenian Intellectual Property Office. This is a recognition of the strength of our product and provides legal commercial protection for our Company and our partner's IP.*

We are continuing to consistently build on the foundations that we have established in bringing our products to the central market and are proud of the progress we have made thus far. The grant of this Patent advances our European focus and affirms our commitment to treating patients with serious conditions on a global scale."

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Authorised for release by the Managing Director, for further information please contact:

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

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

³ Source: <https://www.uptodate.com/contents/evaluation-and-management-of-drug-resistant-epilepsy>

⁴ Source: <https://www.epilepsy.ie/content/prevalence-epilepsy-ireland-study#:~:text=The%20study%20revealed%20that%20there,this%20number%20may%20be%20increasing.>

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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