

11 April 2023

ASX Code: MXC

LSE Code: MXC

CannEpil® now available by Named Patient Request in UK

Highlights:

- **CannEpil®**, MGC Pharma’s Investigational Medicinal Product (“IMP”) is now available in the United Kingdom by Named Patient Request to be prescribed by doctors on The General Medical Council (“GMC”) specialist register across the UK.
- The products will be supplied in order to meet the needs of an individual patients where an unmet medical need exists.
- The availability via Named Patient Request follows the announcement¹ that MGC Pharma is providing **CannEpil®** to an observational trial supported by the *I am Billy Foundation*.
- **CannEpil®** is in the process of a clinical development programme for patients suffering from Refractory (or Drug-Resistant) Epilepsy.

MGC Pharmaceuticals Ltd (‘MGC Pharma’ or ‘the Company’) a European based pharmaceutical company specialising in the production and development of plant inspired medicines, is pleased to announce that the Company’s proprietary product, **CannEpil®** is now available to patients in the UK by Named Patient Request. The listing enables **CannEpil®** to be prescribed by clinicians in the UK who are listed on the GMC Specialist Register, a significant sub section of the United Kingdom’s central doctors register (GMC Register).

CannEpil®

The **CannEpil®** IMP formulation is a high-CBD, low-THC formulation, delivered by oral mucosal solution, part of a clinical development program for patients suffering from Refractory Epilepsy (also known as *Drug Resistant Epilepsy*). A safety study completed in Australia showed **CannEpil®** was safe for post-treatment driving activities.² In 2019, **CannEpil®** was made available for distribution and prescription in Ireland under full governmental health insurance coverage, making it the first product available with coverage in the Republic of Ireland under the Long Term Illness and General Medical Services schemes. Hundreds of patients have been prescribed **CannEpil®** across Australia and the Republic of Ireland over the past three years.

The data collected from the patients will be used to further evaluation of the safety and efficacy of the drug and will support future submissions for marketing authorisation.

Epilepsy

Epilepsy accounts for a significant proportion of the world’s disease burden, affecting around 50 million people worldwide. The estimated proportion of the general population with active epilepsy (i.e. continuing seizures or with the need for treatment) at a given time is between 4 and 10 per 1000 people.³ 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 at least two antiseizure medications (called ASMs).⁴

¹ Refer to ASX Announcement dated 15 March 2023

² ASX Announcement 15/8/22

³ <https://www.who.int/news-room/fact-sheets/detail/epilepsy>

⁴ <https://www.epilepsy.com/learn/drug-resistant-epilepsy>

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CBD has been proven to be effective in the sustained reduction of seizure frequency and severity for epilepsy, which has been supported by open-label studies, observational studies, Randomised Clinical Trials (RCTs) and large-scale systematic reviews.⁵

Roby Zomer, Managing Director and CEO of MGC Pharmaceuticals, commented: “The availability of **CannEpi**® by Named Patient Request marks a momentous breakthrough for MGC Pharma. The product will now be available to a wide cohort of specialist medical practitioners in the UK, which is testament to the progress we are making.”

“**CannEpi**’s® availability in the UK for unmet medical need by doctors on the GMC specialist register, is another material milestone for the company within the healthcare and Life-Science sector as an innovative plant-inspired pharmaceutical company”.

“Stepping up to the Early Patient Scheme is a significant demonstration of our Pharma footprint, and is a step closer to our goal to be available to more patients in need for standardised affordable treatment”.

“We are extremely proud of the progress we have achieved thus far, and we are pleased that **CannEpi**® has been selected as a treatment within an observational patient trial in association with the I am Billy Foundation. We look forward to updating the market on the results of this trial in due course”.

Authorised for release by the board of directors, for further information please contact:

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About GMC Specialist Register

The Specialist Register is a list of doctors who are eligible to take up appointment in any fixed term, honorary or substantive consultant post in the NHS, although specialist registration is not a legal requirement for these posts in foundation trusts.

If a doctor is on the Specialist Register, it will say so as part of their status on the medical register. Doctors can practice in a specialty not shown on their Specialist Register entry. In most cases, they must be on the Specialist Register in at least one specialty to practise as a consultant in any of the UK health services.

The GMC Specialist Register works to protect patient safety and support medical education and practice across the UK. They do this by working with doctors, employers, educators, patients, and other key stakeholders in the UK's healthcare systems. There are more than 359,000 doctors on the UK full Medical Register of which 108,000 are on the Specialist Register

⁵ <https://volteface.me/app/uploads/2022/11/Volteface-Report--Known-Unknowns.pdf>

About I am Billy

I am Billy is a foundation set up to aid parents and families in navigating the challenges of obtaining NHS-funded Medical Cannabis for children. The foundation provides financial assistance in meeting the cost of cannabis based medical products (CBMPs) prescribed by a medical consultant, in addition to advancing the public understanding of the medical benefits of CBMPs.

About MGC Pharma

MGC Pharmaceuticals Ltd (LSE: MXC, ASX: MXC) is a European based pharmaceutical company, focused on developing and supplying accessible and ethically produced plant inspired medicines, combining in-house research with innovative technologies, with the goal of finding or producing treatments to for unmet medical conditions.

The Company's founders and executives are key figures in the global pharmaceuticals industry and the core business strategy is to develop and supply high quality plant inspired medicines for the growing demand in the medical markets in Europe, North America and Australasia.

MGC Pharma has a robust development pipeline targeting two widespread medical conditions and has further products under development.

MGC Pharma has partnered with renowned institutions and academia to optimise the development of targeted plant inspired medicines, to be produced in the Company's EU-GMP Certified manufacturing facilities.

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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