

## First CannEpi<sup>®</sup> delivered to UK patients through I AM Billy Foundation and GMC Specialist Register

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### Highlights

- CannEpi<sup>®</sup>, MGC Pharma's Investigational Medicinal Product ("IMP") has now been successfully imported and received by its first patients in the United Kingdom.
- The first UK patient has received CannEpi<sup>®</sup> through the 'I AM Billy Foundation', supporting the RESCAS study.
- Additionally, the Company has delivered CannEpi<sup>®</sup> to its first patient in the UK via the Named Patient Request programme.
- This follows the announcement on 11 April 2023 that CannEpi<sup>®</sup> was now available in the United Kingdom via Named Patient Request, and available to be prescribed by doctors on The General Medical Council ("GMC") specialist register across the UK.
- CannEpi<sup>®</sup> is in the process of a clinical development programme for patients suffering from refractory (or drug-resistant) epilepsy.

**MGC Pharmaceuticals Ltd** ("MGC Pharma", "MGC" or the "Company") a European based pharmaceutical company specialising in the production and development of plant inspired medicines, is pleased to announce that CannEpi<sup>®</sup>, MGC Pharma's IMP has now been successfully imported and received by its first patients in the United Kingdom.

### CannEpi<sup>®</sup>

The CannEpi<sup>®</sup> IMP formulation is a high-CBD, low-THC formulation, delivered by an oral mucosal solution and is part of MGC's clinical development programme for patients suffering from refractory epilepsy (also known as drug-resistant epilepsy). A safety study completed in Australia showed that CannEpi<sup>®</sup> was safe for post-treatment driving activities<sup>1</sup>. In 2019, CannEpi<sup>®</sup> was made available for distribution and prescription in Ireland under full governmental health insurance coverage, making it available in the Republic of Ireland under the Long-Term Illness and General Medical Services schemes<sup>2</sup>.

MGC Pharma has consistently supported research into refractory epilepsy, which is an important area of unmet medical need and will be providing both its investigational medicine CannEpi<sup>®</sup> and the proprietary ZAM app. As previously announced on 15 March 2023 the app will record daily metrics from patients, their symptoms, and the impact of their treatment in order to establish a baseline. This will provide both medical practitioners and MGC Pharma with a detailed record of the study and an enhanced understanding of the effect of CannEpi<sup>®</sup> on refractory epilepsy patients.

### I AM Billy Foundation

The I AM Billy Foundation is led by Charlotte Caldwell whose epileptic son Billy caused changes to the law when he was granted the first NHS prescription for medical cannabis in 2018 after medications his mother flew in from Canada were seized at Heathrow Airport. Currently, around 25,000 people in the UK are being treated with medical cannabis for conditions including chronic pain, epilepsy, and Parkinson's disease, though the vast majority of prescriptions have been issued through expensive private healthcare schemes with patients struggling to get access to the medicines via the NHS.

<sup>1</sup> Refer to ASX Announcement dated 15 August 2022

<sup>2</sup> Refer to ASX Announcement dated 3 December 2019

MGC Pharma provided CannEpi<sup>®</sup> to the I AM Billy Foundation through the NHS's Refractory Epilepsy Specialist Clinical Advisory Service, currently the only route in the UK for patients to receive public funding for cannabis-based treatments of refractory epilepsy.

Additionally, CannEpi<sup>®</sup> has been received by the first patient in the UK via Named Patient Request. This enables CannEpi<sup>®</sup> 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 (the GMC Register).

**Roby Zomer, Managing Director and CEO of MGC Pharma, commented:** "The fulfilment of the first UK patient to receive CannEpi<sup>®</sup> undergoing the RESCAS process demonstrates the commitment of MGC Pharma to improve patient access to effective epilepsy treatment".

"We know there is a huge unmet need for epilepsy treatment, and we are pleased to be partnering with I AM Billy Foundation on this important work. With our combined knowledge, expertise, and capabilities, our aim is to facilitate patient access to the highest-quality cannabis-based medicinal products for patients with this huge unmet need".

"Additionally, with CannEpi<sup>®</sup> being prescribed via Named Patient Request for the first time, MGC Pharma is making significant progress in its mission to widen access to effective refractory epilepsy treatment and breaking the glass ceiling of such products to support unmet medical needs in the United Kingdom and Ireland, with other key territories hopefully to shortly follow this lead."

-Ends-

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

**MGC Pharmaceuticals Ltd**

Roby Zomer  
CEO & Managing Director  
+61 8 6382 3390  
[info@mgcpharma.co.uk](mailto:info@mgcpharma.co.uk)

**UK Brokers**

**Peterhouse Capital**

Charles Goodfellow / Lucy Williams / Duncan Vasey  
+44 207 469 0930  
[cg@peterhousecap.com](mailto:cg@peterhousecap.com) / [lw@peterhousecap.com](mailto:lw@peterhousecap.com)

**UK IR/PR Advisers**

**IFC Advisory**

Graham Herring / Tim Metcalfe / Zach Cohen  
+44 203 934 6630  
[mgcpharma@investor-focus.co.uk](mailto:mgcpharma@investor-focus.co.uk)

**MGC Pharmaceuticals Ltd**

Arron Canicais / Rowan Harland  
Joint Company Secretaries  
+61 8 6382 3390  
[info@mgcpharma.co.uk](mailto:info@mgcpharma.co.uk)

**UK Brokers**

**Oberon Capital**

Aimee McCusker / Adam Pollock  
+44 203 179 5300  
[aimeemccusker@oberoninvestments.com](mailto:aimeemccusker@oberoninvestments.com)  
[adampollock@oberoninvestments.com](mailto:adampollock@oberoninvestments.com)

## 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

## About 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<sup>3</sup>. 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)<sup>4</sup>. There are 600,000 people with epilepsy living in the UK, around one in every 100 people. Every day, 87 people are diagnosed. One in every four people newly diagnosed with epilepsy is over the age of 65. One in 67 older people have epilepsy and this number is likely to keep increasing.

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

<sup>4</sup> <https://www.epilepsy.com/treatment/medicines/drug-resistant-epilepsy>