

13 September 2021

ASX Code: MXC

LSE Code: MXC

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## Landmark UK Import Permit granted for MGC Pharma’s CannEpil+, designed to treat Refractory Epilepsy

### Key Highlights:

- **CannEpil+**, based on CannEpil™, designed by MGC Pharma to treat Refractory Epilepsy, has been approved for import into the UK by the Medicines and Healthcare products Regulatory Agency via its UK distribution and clinical access partner Elite Pharmaco.
- This is the first time that an epilepsy treatment currently in a Clinical Trial process, and containing THC, has been approved by the authorities in the UK for import.
- Landmark milestone achieved by the Company in the UK, opening a key strategic market for its leading phytocannabinoid derived medicine.
- **CannEpil+** will be made available for free on compassionate grounds to ten patients for six months, whose treatment will be monitored as part of an observational trial using a Data Collection App, provided by Alta Flora. This app will provide real time data on the efficacy of **CannEpil+** to the regulatory bodies, and Doctor’s monitoring its effectiveness as a treatment.
- One of the most common serious neurological conditions, Epilepsy affects approximately 600,000 people in the UK, and ~50 million people worldwide,<sup>1</sup> with approximately 33% of adults, and 20-25% of children, suffering from Refractory Epilepsy (or Drug Resistant Epilepsy) which cannot be controlled with traditional anti-seizure medication.<sup>2</sup>

**MGC Pharmaceuticals Ltd** (‘MGC Pharma’ or ‘the Company’), a European based bio-pharma company specialising in the production and development of phytocannabinoid-derived medicines, is pleased to announce that **CannEpil+**, a Biosimilar effect-identical product of **CannEpil™**, which is a phytocannabinoid treatment for Refractory (or drug-resistant) Epilepsy, has been approved for UK import by the Medicine and Healthcare products Regulatory Agency (**MHRA**), which was facilitated by its UK distribution and clinical access Partner, Elite Pharmaco. As part of this process, **CannEpil+** has been approved for prescription for patients in the UK.

**CannEpil+** will initially be used to treat ten patients in the UK who suffer from Refractory Epilepsy. MGC Pharma will be providing **CannEpil+** free of charge to these patients on compassionate grounds for six months. This is the first time that the UK authorities have approved an Epilepsy treatment that is on a clinical pathway (Phase IIB) containing THC.

The approval to import **CannEpil+** into the UK is in response to the urgent need of some patients to have access to a clinical product which has demonstrated its efficacy at treating Refractory Epilepsy, as well as its safety.

Once the patients have commenced their treatment, **CannEpil+** will undergo an observational trial with data being entered into a Data Collection App designed to establish a central platform to monitor the safety of treatment in patients globally.

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

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

MGC Pharma expects that the results from the observational data collection program, together with the fact that **CannEpil™** has historical clinical safety and efficacy data, and a Phase IIb Clinical Trial that is currently under negotiation with a UK NHS facility, will provide specialist neurologists and general practitioners with the confidence to prescribe **CannEpil™** and **CannEpil+** to patients in urgent need of treatment.

### **MHRA Approval and Prescription Approval**

Now officially approved for import into the UK, a doctor can issue a prescription for **CannEpil+** for both adults and children. There are currently 10 patients who will have access to **CannEpil+** on compassionate grounds, who will be the first to be prescribed the treatment.

### **About CannEpil+**

**CannEpil+** is a Biosimilar effect-identical product of **CannEpil™**, manufactured under strict EU-GMP conditions, and can be provided to patients in countries which allow Cannabis Based Medical Products. This distinction allows MGC to offer **CannEpil+** at more affordable price to patients globally, as the Company moves through the Clinical Trial pipeline with **CannEpil™**.

**CannEpil™** is MGC's IMP (Investigational Medical Product) formulation, currently undergoing Phase IIb trials and pipelined for Central Market Authorisation in the next 2 years. This product can only be manufactured in specific facilities, for the purpose of either Clinical Trials or Early Access Schemes.

### **Data Collection App**

MGC and Alta Flora have together created a bespoke version of the Eva App, a healthcare data platform which enables researchers and the medical establishment to determine how plant-based therapies improve patient quality of life. The system captures Patient Reported Outcome Measures which can be used by regulators, manufacturers and clinicians to assess the safety and efficacy of new medicines.

The functionality of the App will enable the adjustment of measurement protocols in order to meet clinical standards, and to incorporate other conditions and future observational trials for their treatment.

### **Refractory Epilepsy**

Refractory or Drug Resistant Epilepsy affects approximately 33% of adults and 20-25% of children suffering from Epilepsy. In the UK, there is a national prevalence of treated Epilepsy of 1 in 100 people, and around 87 people are diagnosed with Epilepsy in the UK every day.<sup>3</sup>

Further Phase IIb randomised, double blind, placebo-controlled clinical studies are to begin in Q3 and Q4 2021 (refer announcement 25<sup>th</sup> May 2021). This will take place at the Schneider Hospital in Israel and within the NHS in the UK. It will focus on the safety and efficacy of **CannEpil+** as a supplementary treatment in children and adolescents with Refractory Epilepsy.

**Roby Zomer, Co-founder and Managing Director of MGC Pharma, commented:** “The approval for the import of **CannEpil+** to the UK and the associated compassionate prescriptions is an important step towards our global roll out of the treatment, and our continued commitment to patients. Achieving MHRA approval has been an ongoing process for some time with our UK partner Elite Pharmaco, and we expect the first patients in the UK to begin treat with **CannEpil+** in the coming months.

The development of our Data Collection App will optimise our understanding of both **CannEpil™**, **CannEpil+** and other future treatments, and ultimately provide patients with a better treatment for Refractory Epilepsy, and therefore improving their quality of life. It is also a vitally important foundation for building strong relationships with UK medical regulators and health organisations which will benefit MGC Pharma going forward, as we look to roll out further clinical trials and products in the UK.”

**Robin Emerson COO of Elite Growth Ltd and high-profile Medical Cannabis Advocate commented** “This is a huge step forward for cannabis-based medications in the UK. As a father of a 5-year-old girl I have witnessed first-hand how

<sup>3</sup> Source: <https://www.epilepsy.org.uk/info/what-is-epilepsy>

Jorja’s life has been transformed by the use of a Cannabis based medication that contains THC. With this product approval patients that have tried everything else now have a product with some level of safety and efficacy for the treatment of epilepsy that can be prescribed by their physician. With the ongoing clinical trial portfolio that MGC Pharma have developed, including a near term UK NHS based trial, we are answering the call of clinicians in the UK who are asking for safety and efficacy data. The CannEpi+ programme we are executing will go a long way to moving cannabis-based medications toward greater adoption and acceptance, opening up much needed access for patients in the UK.

**Gavin Sathianathan, CEO of Alta Flora said:** “MGC Pharma have stepped up to the challenge to provide access to life-changing medicine for ten trial patients, and Alta Flora is proud to support the effort to gather data in order to demonstrate that CannEpi+ has the potential to transform the quality of life of families struggling to deal with the consequences of childhood epilepsy syndromes”

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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 phytocannabinoid derived medicines 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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## About Elite Pharmaco

Elite Pharmaco LTD, a UK based company, and its subsidiary Elite Growth Ltd, are companies specialising in medical distribution, product development and clinical trial market access. Elite is increasingly being recognised as the leading specialist in helping producers in the field of Cannabis based medications and bio-pharma products to gain access and successfully launch products in the UK market.

## About Alta Flora

Alta Flora's healthcare data platform enables researchers and the medical establishment to determine how plant-based therapies improve patient Quality of Life. The system captures Patient Reported Outcome Measures through an app called Eva which can be used by regulators, manufacturers and clinicians to assess the safety and efficacy of new medicines. Eva is available for free in the iOS and Android app stores and is fully GDPR compliant.