

15 June 2021
ASX Code: MXC
LSE Code: MXC

CannEpi[®] added to Primary Care Reimbursement Service in Ireland for full patient cost rebate

Key Highlights:

- CannEpi[®] has been added to the Primary Care Reimbursement Service in the Republic of Ireland (“Ireland”) as part of the Medicinal Cannabis Access Programme (“MCAP”), making it free of charge for Irish patients prescribed the treatment under the MCAP.
- CannEpi[®] is one of the first EU-GMP pharmaceutical grade cannabis medicine products to be approved for prescription in Ireland under the MCAP and under the Primary Care Reimbursement Service, which is part of Ireland’s Health Service Executive (“HSE”).
- This announcement follows the approval for distribution and prescription of CannEpi[®] by Ireland’s Department of Health in December 2019 (refer announcement 3rd December 2019).
- CannEpi[®], which is designed to treat Refractory Epilepsy, also known as Drug Resistant Epilepsy, will enter a Phase IIb Clinical Trial during Q3 2021 (refer announcement 25th May 2021).
- Approximately 40,000 people in Ireland, and ~50 million people worldwide¹ suffer from epilepsy, 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 medication².
- MGC delivers record sales of its core phytocannabinoid derived medicine products in May, with its highest monthly revenue of more than A\$360,000, which excludes Artemic[™] sales.

MGC Pharmaceuticals Ltd (ASX, LSE: MXC, ‘MGC Pharma’ or ‘the Company’), a European based bio-pharma company specialising in the production and development of phytocannabinoid-derived medicines, announces that its cannabis derived epilepsy Investigational Medicinal Product (“IMP”), CannEpi[®], will now be fully covered by the HSE in Ireland. This follows the incorporation of the MCAP into the HSE’s Service Plan, and under which CannEpi[®] is an approved product for medical use, as defined in the legislation (refer announcement 3rd December 2019).

Approval of CannEpi[®] to the HSE Service Plan

CannEpi[®] is a phytocannabinoid derived IMP, designed to treat Drug Resistant Epilepsy with a high CBD, low THC formula, and was made available for distribution and prescription in Ireland in 2019 as part of the MCAP. In January 2021, the Irish Department of Health announced provision for the delivery and funding of the MCAP through its inclusion in the HSE’s Service Plan. CannEpi[®] is an approved product for medical use and will be available free of charge to patients under the Long-Term Illness Scheme, GMS (Medical Card) Scheme, and the Drugs Payment Scheme on a named-patient basis, as defined in the legislation.

Medical professionals in Ireland can prescribe CannEpi[®] for patients under their care for a range of medical conditions in addition to Epilepsy. Other indications that CannEpi[®] has already been prescribed for are Anxiety, Chronic Pain, Insomnia, PTSD and Parkinson’s Disease, all under Cannabis Access Schemes.

CannEpi[®] is already being prescribed in Australia and the UK in the treatment epilepsy.

CannEpi[®] is available through our Irish partner Georgelle Ltd. Georgelle is one of Ireland’s leading wholesale pharmaceutical companies, supplying the country’s network of hospitals and retail pharmacies with Licensed & Exempt Medicinal Products.

¹ Source: <https://www.epilepsy.ie/content/epilepsy-explained>

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

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Epilepsy is prevalent worldwide, with over 50 million people suffering from seizures. Refractory (treatment-resistant) Epilepsy affects approximately 33% adults and 20-25% of children already suffering from epilepsy. In Ireland, there is a national prevalence of treated epilepsy of 9 per 1,000 people for those over the age of 5, meaning an estimated 37,000 epilepsy patient population.³

Further Phase IIb randomised, double blind, placebo controlled clinical studies are to begin in Q3 2021 (refer announcement 25th May 2021). This will take place at the Schneider Hospital in Israel and will focus on the safety and efficacy of CannEpi[®] as a supplementary treatment in children and adolescents with Refractory Epilepsy.

Record monthly revenues of Phytocannabinoid medicine products in May

The Board is pleased to report that the Company continues to execute on the global sales strategy of its phytocannabinoid derived medicines, with May delivering its best monthly revenue to date of more than A\$360,000.

This monthly sales revenue of over A\$360,000 excludes all non-cannabinoid products including the material ArtemiC[™] supply contracts announced in 2021, demonstrating the continued and strengthening sales pipeline within its core phytocannabinoid business, led by the Company’s Global Chief Sales Officer Nicole Godresse. With recent developments including the inclusion of CannEpi[®] on the HSE Service Plan for the Republic of Ireland, the Company is well positioned to continue the growth of the commercial side of the business through H2 2021 in line with its core business milestones.

Roby Zomer, Co-founder and Managing Director of MGC Pharma, commented: “This is a key moment for MGC Pharma and for the Irish patients who can now receive cannabis-based treatments covered by the National Health Insurance. Furthermore, this is a critical moment in the roll out of CannEpi[®] both in Ireland and worldwide. Our goal is to improve the lives of people who suffer with Refractory Epilepsy and other indications, and by making CannEpi[®] available free to access for patients in Ireland, this will now be the case. Combined with record monthly sales in May for our leading phytocannabinoid derived medicines, the Company continues to deliver on its goal of building a strong and sustainable global bio-pharma business.

With further Clinical Trials of CannEpi[®] underway, we hope to be able increase the supply and availability of the medicine in the most affordable way to epilepsy sufferers globally in the near future.”

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Authorised for release by the Board, for further information please contact:

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³ Source: The prevalence of Epilepsy in Ireland

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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