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Approval Received for Immediate Distribution and Prescription of CannEpi[®] in Ireland – Opening to key EU markets

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MGC Pharmaceuticals Ltd (ASX: MXC, ‘MGC Pharma’ or ‘the Company’), a European based ‘Seed to Medicine’ bio-pharma company focused on developing and commercialising phytocannabinoid derived medicines, is pleased to announce it has received formal approval for the sale of CannEpi[®] in Ireland following the recommendation by the Health Products Regulatory Authority (HPRA), CannEpi[®] is one of MGC Pharma’s Investigational Medicinal Product’s (IMP) to treat drug resistant epilepsy. These approvals have now been officially granted by the Irish Ministry of Health, to be one of the first cannabinoid-based medicines approved for prescription and sale under the Irish Government’s Medical Cannabis Access Programme.

Key Highlights:

- Approval received from Ireland’s Ministry of Health permitting the sale of MGC Pharma’s phytocannabinoid derived medicine CannEpi[®] under the Medical Cannabis Access Programme
- Approval enables the immediate prescribing of CannEpi[®] in Ireland, which is manufactured at MGC Pharma’s EU-GMP certified production facility in Slovenia
- Irish Doctors already in contact with MGC Pharma’s distributor to prescribe first patients
- Ireland is a key EU member state country to grant approval for the prescription and sale of MGC Pharma phytocannabinoid derived products
- CannEpi[®] is the one of the first EU-GMP, pharmaceutical grade cannabis products to be approved for prescription in Ireland under the Medical Cannabis Access Programme
- CannEpi[®] is the Company’s phytocannabinoid derived formulation targeting the treatment of drug resistant epilepsy - high CBD, low THC formula (20:1)
- The Company anticipates the Irish approval of MGC Pharma’s phytocannabinoid derived products to accelerate the approval process in other EU member states through ‘mutual recognition’
- 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 37,000¹ epilepsy patient population
- The country has seen a gradual year-on-year increase in the prevalence of treated epilepsy¹

Roby Zomer, Co-founder and Managing Director of MGC Pharma, commented: “Access to the Irish market is a key achievement for the Company. Not only does it allow MGC Pharma’s GMP certified medical products to reach more patients in need, but can be seen as a catalyst for fast-tracking follow-on approval applications to prescribe in other EU member state countries such as Germany, Austria, Italy and France. With distribution agreements already in place across Europe, we are well positioned for a quick entry to these markets following receipt of the required approvals.

¹ Source: [Epilepsy Ireland- The Prevalence of Epilepsy in Ireland study](#)

“The sale of CannEpi[®] into Ireland is now able to commence, with the first shipment now imminent. With an increasing number of patients being treated for drug resistant epilepsy in Ireland, we believe that the high levels of demand from patients and doctors witnessed in the UK and Australia will be replicated in Ireland as doctors and patients familiarise themselves with MGC Pharma’s high quality, affordable phytocannabinoid derived medicines.”

Further Information

The Irish Ministry of Health has issued approval to MGC Pharma enabling the lawful prescription and sale of its phytocannabinoid derived medicine, CannEpi[®] into Ireland under the Medical Cannabis Access Programme, following a recommendation by the Health Products Regulatory Authority (HPRA). CannEpi[®] is a phytocannabinoid derived formulation targeting the treatment of drug resistant epilepsy. Approval enables the immediate sale of CannEpi[®] in Ireland from MGC Pharma’s EU-GMP certified production facility in Slovenia. Following this approval, as per Australia and the UK, import approval for MGC Pharma products will be granted per shipment into Ireland.

Importation into Ireland will also be managed through our UK distributors Grow Biotech PLC, a British headquartered company developing industry-leading processes, practices, techniques, tools and formulations to bridge the gap between existing cannabis medicines and accepted pharmaceutical standards.

The Medical Cannabis Access Programme sits under The Misuse of Drugs (Prescription and control of supply of cannabis for medical use) Regulations 2019. The Regulations enable the importation, prescription and supply of cannabis-based products that have met specific requirements on quality and safety, which must be approved by the Health Products Regulatory Authority. Once approved, medical professionals can prescribe a product for one of three approved conditions (including drug resistant epilepsy), where the patient has failed to respond to standard treatments.

Now that CannEpi[®] has been approved under the Medical Cannabis Access Programme in Ireland, the Company intends on leveraging the procedure for mutual recognition within the EU and key Member States, where authorisation of a medicine in one Member State is recognised by another Member State.

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This announcement was authorised by the Board

For further information, please contact:

UK IR/Media Advisors

Catherine Leftley/Megan Dennison
St Brides Partners Ltd
+44 (0) 207 236 1177
megan@stbridespartners.co.uk
catherine@stbridespartners.co.uk

MGC Pharmaceuticals Ltd

Brett Mitchell
Executive Chairman
+61 8 6382 3390
info@mgcpharma.com.au

About MGC Pharma

MGC Pharmaceuticals Ltd (ASX: MXC, OTCQB: MGCLF) is a European based bio-pharma company supplying 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 three widespread medical conditions - epilepsy, dementia and IBS – and has further products in the development pipeline.

Employing its 'Seed 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 recent research conducted in collaboration with the National Institute of Biology and University Medical Centre Ljubljana, highlighted the positive impact of using specific phytocannabinoid formulations 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 and the UK and has a global distribution footprint via an extensive network of commercial partners meaning that it is poised to supply the global market. In order to meet the demands of becoming a key global supplier the company is constructing a 15,720m² GMP state of the art facility in Malta.

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