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Head-to-head Epilepsy clinical study comparing CannEpi™ to 100% CBD receives Ethics Committee approval

ASX
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ANNOUNCE

MGC Pharmaceuticals Ltd (ASX: MXC, 'MGC Pharma' or 'the Company'), a European based 'Seed to Pharmacy' bio-pharma company focused on developing and commercialising phytocannabinoid derived medicines, is pleased to announce that it has received Human Research Ethics Committee (HREC) approval to conduct a head-to-head clinical study on severe intractable epilepsy in collaboration with Cannabis Access Clinics and Epilepsy Action Australia. This is one of the first studies in the world to conduct a direct comparison assessing the efficacy of low-THC to 100% CBD products when treating severe intractable epilepsy.

The study will consist of 100 epilepsy patients treated with either CannEpi™ or MXP100, with difference in efficacy analysed. CannEpi™ is a high Cannabidiol (CBD), low Tetrahydrocannabinol (THC) formula (20:1) developed for the treatment of drug resistant epilepsy and is the Company's proprietary pharmaceutical grade phytocannabinoid derived medicine authorised for prescription as an Investigational Medicinal Product (IMP) in both Australia and the United Kingdom currently, with regulatory approval underway in a number of other countries. MXP100 is the Company's CBD-only formula containing 100mg/mL of CBD available under Australia's Special Access Scheme.

Key Highlights:

- Head-to-head clinical study to compare the efficacy of CannEpi™ and MXP100 in the treatment of severe intractable epilepsy (the Study)
- The Study will be one of the first clinical opportunities in the world to assess and collect several data points – Long term safety of THC, efficacy of cannabinoid treatments vs. current available treatments, and very crucially – medical community education process and Doctors assessments on cannabinoid medicine's long-term impact on quality of treatment and quality of life
- The head-to-head study will be one of the first in the world to assess the efficacy of low-THC to 100% CBD products when treating severe intractable epilepsy
- Study to be conducted on approximately 100 patients from Cannabis Access Clinics with half being treated with MXP100 and the other half treated with CannEpi™
- Formal endorsement received from Epilepsy Action Australia including assistance with patient recruitment

Roby Zomer, Co-founder and Managing Director of MGC Pharma, commented: "This direct comparative head-to-head study on the use of phytocannabinoid derived products on the treatment of severe epilepsy is hoped to begin to demonstrate the increased efficacy of CannEpi™, and is an example of MGC Pharma's commitment to being at the forefront of research and innovation in the sector, leading to increased patient access. As such, we are delighted to have received approval from the HREC which enables us to immediately start the study connecting patients in need with MGC Pharma's products and providing valuable information and data on the effectiveness of phytocannabinoid based treatments and epilepsy."

Dr Sanjay Nijahawan, Medical Director Cannabis Access Clinics, commented: "We see a lot of epilepsy patients in our clinics and we hope that studies like this will help doctors understand more about the clinical benefits of medicinal cannabis and best to prescribe it for their patients."

Carol Ireland, CEO of Epilepsy Action Australia, commented: “Epilepsy Action Australia is always happy to see more research being conducted on the benefits of cannabis treatments for epilepsy, as continued positive results will assist in ensuring it becomes mainstream. However, there are still many issues other than research facing patients in Australia, and globally, for obtaining access to such potentially life-changing medications. We look forward to continue working with MGC Pharma to address these.”

Additional Information

Human Research Ethics Committee (**HREC**) approval has recently been received by MGC Pharma and Cannabis Access Clinics to conduct a head-to-head clinical study comparing the efficacy of CannEpiTM and MXP100 on the treatment of severe intractable epilepsy, in collaboration with Epilepsy Action Australia.

CannEpiTM is a high CBD, low THC formula (20:1) developed for the treatment of drug resistant epilepsy and is the Company’s proprietary pharmaceutical grade phytocannabinoid derived medicine authorised for prescription as an Investigational Medicinal Product (**IMP**) both in Australia and the United Kingdom. MXP100 is the Company’s CBD-only formula containing 100mg/mL of CBD available under Australia’s Special Access Scheme.

While there is a growing body of evidence that phytocannabinoid derived medicines may reduce seizures in epilepsy patients, much of this data is for cannabidiol (**CBD**) only products. There is increasing data, from both the Company’s research on CannEpiTM, and other studies using similar formulations, that low tetrahydrocannabinol (**THC**) high CBD medicines may have greater efficacy.

This will be one of the first studies to directly compare the two, and if successful, will provide additional evidence that CannEpiTM may have a significant positive impact on patients with epilepsy in Australia, and for distribution into the global marketplace.

Approval from the HREC enables the study to commence immediately, with 100 adult patients from Cannabis Access Clinics participating in the study, with 50 being treated with CannEpiTM and 50 being treated with MXP100. Each patient will be monitored for 12 months on the Company’s products. Epilepsy Action Australia has endorsed the study and will assist through providing support in the recruitment of patients.

The primary outcome is Patient Reported Outcome Measures (**PROM**), which measures and tracks the patient’s seizures, include duration, rescue medication (if any), seizure type, possible triggers, location, etc. All patients will be monitored with no medication to establish a baseline for four weeks prior to taking either CannEpiTM or MXP100, they will then be monitored for 12 months while taking CannEpiTM or MXP100. Secondary outcome is Patient-Reported Outcomes Measurement Information System (**PROMIS-29**), which is used to measure self-reported physical, mental and social health, and wellbeing.

Following this approval from the HREC, participant recruitment is expected to commence Q4CY2019 once all import/export permits are granted, which are currently being obtained by the Company. Once participant recruitment has commenced the Study will proceed with data collection, data analysis and data reporting with the Company expecting the final report within 24 months of commencement.

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About MGC Pharma

MGC Pharmaceuticals Ltd (ASX: MXC, OTCQB: MGCLF) is an EU-based BioPharma company with many years of technical clinical and commercial experience in the medical cannabis industry. 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 cannabinoids-based pharmaceuticals products for the growing demand in the medical markets in Europe, North America and Australasia.

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About Cannabis Access Clinics

Cannabis Access Clinics (CAC) is a Southern Cannabis Holdings company and is the largest network of medicinal cannabis clinics in Australia. CAC work directly with patients who suffer from indications for which there is some evidence that medicinal cannabis therapies may be beneficial. They work in accordance with TGA Guidance documents on medicinal cannabis, consulting patients with a number of indications.

To find out more on Cannabis Access Clinics, please visit: www.cannabisaccessclinics.com.au

About Epilepsy Action Australia

Epilepsy Action Australia is the country's leading patient support organisation, leading the way in ensuring those affected have the skills and knowledge to live the very best life possible. As the leading and oldest provider of epilepsy services nationwide, they focus on improving self-management skills, increasing wider public understanding of this devastating condition, and are at the forefront of partnering and funding research into interventions and treatments. EAA has also been at the forefront of advocating for patient access to medicinal cannabis medications.

To find out more on Epilepsy Action Australia, please visit: www.epilepsy.org.au and for patient education on the endocannabinoid system and medicinal cannabis go to www.c4e.com.au