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ASX Code: MXC

Ethics Committee Approval Received for CannEpil® Phase IIb clinical trial in Israel

ASX RELEASE

Key Highlights:

- Ethics committee approval received for a Phase IIb clinical trial for MGC Pharma's proprietary formulation CannEpil® designed to treat drug resistant epilepsy
- The clinical trial will be a randomised, double blind, placebo controlled, parallel design Phase IIb study conducted at the Schneider Children's Medical Center of Israel
- Trial to assess the safety and efficacy of CannEpil® in children and adolescents with drug resistant epilepsies
- 103 patients aged between 1 and 18 years will be recruited, and the Trial is expected to last 12 weeks per patient
- Trial expected to commence in September 2020 following final approvals from the Ministry of Health in Israel, with last patient visit in October 2021

MGC Pharmaceuticals Ltd (ASX: MXC, '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 it has received ethics committee approval from Schneider Children's Medical Center of Israel ("**Schneider Hospital**") to commence a phase IIb clinical trial (the **"Trial**") at Schneider Hospital for its proprietary epilepsy treatment, CannEpil®.

The Trial will be a randomised, double blind, placebo controlled, parallel design Phase IIb study of the safety and efficacy of CannEpil® as an add on treatment in children and adolescents with refractory epilepsy, also known as drug resistant epilepsies.

The Trial will recruit 103 patients between the ages of 1 and 18 years old and will be led by Principal Investigator Dr. Dror Kraus at the Schneider Hospital in Israel. The Trial will last for 12 weeks per patient and is expected to commence in September 2020 following the receipt of final approvals from the Ministry of Health in Israel, which are expected in August 2020. Recruitment of patients can commence immediately following receipt of the final Ministry of Health approval for the Trial.

The Trial will be under the supervision of Professor Uri Kramer, the lead of neurological development in MGC Pharma's clinical advisory team. Professor Kramer is a former Director of Paediatric Epilepsy Service at Tel Aviv Sourasky Medical Centre in Tel Aviv, Israel, where he is an acknowledged global expert, and has previously led research regarding medical cannabis treatments for severe cases of epilepsy. He has a wealth of experience in various fields (Neurology, Paediatric Neurology and Child Development).

Results from the Trial will contribute essential data characterising the medicinal value of CannEpil® and determine the subsequent course of action in the Company's pursuit of marketing authorisation for this proprietary preparation. This will be of significant importance to the current and future commercial discussions held by the Company, as it is a material target market for its business. There are over 1,900,000 people with epilepsy in Europe with over 200,000 in Australia[1]. Upon completion of successful clinical trials and receipt of marketing authorisation for CannEpil®, the estimated yearly average annual treatment costs per patient (within the EU) is expected to be $12,000 - $15,000 per patient[1] (as previously announced), before the application of any government rebates.

[1] Source: Alacrita Market Projections Report – October 2019

CannEpil® will continue to be prescribed as an Investigational Medicinal Product (IMP) to patients through MGC Pharma's distribution partners globally under early access and compassionate care schemes.

Full details on the Trial required for compliance with the ASX Code of Best Practice for Reporting by Life Science Companies are included in Annexure A.

Roby Zomer, Co-founder and Managing Director of MGC Pharma, commented: "Receiving ethics committee approval for the Phase IIb clinical trial of CannEpil® is another important milestone for the Company. CannEpil® is one of the Company's lead cannabinoid medicine products with a very significant global market opportunity. Israel is recognised for its world leading researchers and institutions in relation to cannabis products and we look forward to updating the market as this trial progresses."

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Authorised for release by Roby Zomer, CEO & Managing Director. For further information please contact:

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About MGC Pharma

MGC Pharmaceuticals Ltd (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 '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 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 Schneider Children's Medical Center of Israel

Schneider Children's Medical Center of Israel is one of the tertiary leading pediatric hospitals in Israel with a comprehensive epilepsy unit. Since its establishment in 1991, Schneider Children's has revolutionized the practice of pediatric medicine in the country and been recognized as one of the leading pediatric institutions in the world.

Schneider derives its name from its founders and major benefactors, the late Irving and Helen Schneider from New York, who also promoted its legacy to serve as a Bridge to Peace between nations. Through this open-door policy, where all children irrespective of race, religion or nationality are treated, Schneider Children's receives patients from neighboring countries including the Palestinian Authority and Jordan, and from as far away as Africa, Asia and Eastern Europe.

Schneider Children's comprises 250 beds, 43% of which are assigned to critical care (Intensive Care Units, Neonatology, Burns, etc.). The medical center serves as the national referral center for Hematology-Oncology, Endocrinology and Diabetes, Cardiology, and organ and bone marrow transplantation.

ANNEXURE A

Name and any unique identifier of the trial:	Randomized, double blind, placebo controlled, parallel design Phase IIb study of safety and efficacy of CannEpil® as an add on treatment in children and adolescents with resistant epilepsies
Primary endpoint(s):	• The proportion of patients showing a >50% reduction in frequency of seizures at week 12 of the study, in the treatment versus placebo groups • Change in number of epileptic seizures as documented by patient diaries (Day 0 level compared to Week 6 level and Week 12 level) in treatment and placebo group.
Secondary endpoints:	• The incidence of adverse events will be summarized by organ class, severity and duration on weeks 12 and 18 of the study. • Descriptive statistics for clinical observations, laboratory values as well as their change from baseline will be prepared. • Change in score from QOLCE-55 questionnaire as compares between Day 0 level and Week 12 level • Change in Clinical Global Impressions Scale (Day 0 level compared to Week 12 level) by treatment group • Percentage of CannEpil®-treated patients who will develop a response to CannEpil® (response will be defined as a reduction of seizures frequency by at least 25 %) • Proportion of seizure-free patients between the placebo and treatment group on Week 12 of treatment (including titration). Change in form of new seizures and emergency of new forms will be monitored during the trial.
Blinding status:	Double blind
Product status:	CannEpil®is made to GMP standards
Treatment method, route, frequency, dose levels:	CannEpil® (each ml of solution containing 100 mg of cannabidiol and 5 mg of (-)-trans-Δ9-tetrahydrocannabinol as active substance) from MGC PHARMACEUTICALS D.O.O. According to dosing scheme up to 25 mg/kg BW per day or maximum daily dose 800 mg (whichever smaller) for 6 weeks titration and 6 weeks of treatment, oral administration. The patients will be FU for additional 28 days.
Number of trial subjects:	103 patients will be recruited to the study. The randomization will be performed 2:1 active:placebo on study visit 2.
Description of Control Group:	34 patients will get placebo. Randomization codes have been generated with validated computer program and have been kept only by sponsor and CRO (sponsor's production unit and CRO biostatistics and pharmacovigilance department). As neither Investigator nor any other member of site staff including laboratory staff / will have access to randomisations schemes, they will remain blinded throughout the study. Blinding envelopes containing the randomization code for each patient separately will however be stored on site in Investigator Site File to enable emergency unblinding in case of medical emergency.
Subject selection criteria:	Inclusion criteria- 1) Patient has documented clinically confirmed diagnosis of epilepsy; 2) Patient did not respond to at least 2 AED's therapy given in adequate doses; 3) Patients current therapy is considered inadequate (not completely controlled by AEDs); patients had four or more countable seizures with a motor component per 4-week period; 4) Patient is aged 1 year - 18 years inclusive at the time of screening; 5) Patient took one or more AEDs treatment at dose which has been stable for at least 4 weeks before enrolment; 6) Females of childbearing potential can only participate in the study if willing to use acceptable, effective methods of contraception during the trial and for three months after end of trial participation as defined in point 7.10 of this protocol; 7) Patient/parent is able to read/understand informed consent. 8) Male patients must either be surgically sterile or he and his female spouse/partner who is of childbearing potential must be willing to use highly effective methods of contraception consisting of 2 forms of birth control (1 of which must be a barrier method) starting at screening and continuing throughout the study. 9) All medications or interventions for epilepsy (including ketogenic diet and vagus nerve stimulation (VNS) were stable for four weeks prior to screening and participants were willing to maintain a stable regimen throughout the study. The ketogenic diet and VNS treatments are not counted as an AED. Exclusion criteria – 1) Known history or presence of clinically significant unstable medical condition other that epilepsy which, in the opinion of the Investigator, would jeopardize the safety of the subject or impact the validity of the study results. 2) Known history or presence of serious cardiovascular disease 3) Known or suspected history or family history of: schizophrenia, or other psychotic illness, severe personality disorder or other significant psychiatric disorder. 4) Known or suspected allergy hypersensitivity or idiosyncratic reaction to cannabinoids or any other drug substances with similar activity or to any of the excipients of the IMP. 5) Participant has clinically relevant abnormalities in the 12-lead electrocardiogram measured at screening or randomisation.

	6) Patients were currently using or had in the past used recreational or medicinal cannabis or synthetic CBD based medications or preparations within last 3 months or had previous or current treatment with cannabis-based therapy within last 3 months. 7) History of drug or alcohol addiction requiring treatment. 8) History of malabsorption within the last year or presence of clinically significant gastrointestinal disease or surgery that may affect drug bioavailability, including but not limited to cholecystectomy. 9) Presence of hepatic or renal dysfunction. (SGOT and SGPT and bilirubin > X2 UNL. creatinine > 1.5mg/dl); 10) Females who are pregnant (serum hCG level consistent with pregnancy diagnosis); or are lactating; 11) Participation in a clinical trial that involved administration of an investigational medicinal product within 90 days prior to drug administration, or recent participation in a clinical investigation that, in the opinion of the Investigator, would jeopardize subject safety or the integrity of the study results; 12) Participant has clinically significant abnormal laboratory values (e.g. liver enzymes); 13) Participant has clinically significant findings from a physical examination (fever); 14) In case of ketogenic diet or VNS; the diet needs to be stable for at least 4 weeks, and VNS ramping needs to be stable at least 12 weeks before enrolment.
Trial locations:	Israel - Schneider Childrens Medical Center of Israel, Epilepsy Unit
Name of the principal investigator:	Israel – Dr. Dror Kraus
Partners:	CRO – MediCaNL Ltd
Expected duration:	The study is expected to be approved by MoH in August 2020. First patient first visit – September 2020. Last patient last visit – October 2021.
Additional information:	N/A
Trial standard:	The trial will be managed according to the GCP, EMA and FDA requirements.