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ASX Code: MXC

Second Ethics Committee Approval Granted by Leading Israeli Hospital for the Phase II Clinical Trial on COVID-19 Patients

ASX RELEASE

MGC Pharmaceuticals Ltd (ASX: MXC, 'MGC' or 'the Company'), a European based 'Seed to Medicine' bio-pharma company specialising in the production and development of phytocannabinoid-derived medicines, is pleased to announce it has been granted a second Human Research Ethics Committee ('**Ethics Committee**') approval from the Hillel Yaffe Hospital in Israel for an additional site to conduct the Phase II placebo controlled clinical trial to evaluate the safety and efficacy of a natural anti-infective based formulation ('**ArtemiC**' or the '**Product**') on patients diagnosed with COVID-19 (the '**Trial**').

This is a key milestone for the Company and the planned clinical trial on the Product on patients diagnosed with COVID-19, with the validation from a second leading medical hospital in Israel to run the Phase II trial. Hillel Yaffe Hospital is one of the major specialist hospitals in Israel operating since 1957, specialising in organ implants, trauma and general treatments, having served over 450,000 people.

Highlights

- ArtemiC is designed with the scientific aim to target viral infections with inflammatory complications, and is now to be evaluated on novel coronavirus 2019 (SARS-CoV-2) infected patients in a double-blind placebo controlled, Phase II clinical trial
- MGC has received a second Ethics Committee approval from Hillel Yaffe Hospital in Israel, for the Phase II clinical trial to be undertaken on patients diagnosed with COVID-19
- This additional site for the Phase II clinical trial will compliment and strengthen the Trial previously approved by Nazareth Hospital EMMS
- The Trial will evaluate the safety and efficacy of ArtemiC in the treatment of patients diagnosed with COVID-19
- The Trial will provide additional data for claims on the Product as a food supplement, and essential data to plan future trials required to achieve full marketing authorisation of ArtemiC
- Approved as "Special Clinical Trial" there is no requirement for any additional approval from the Israeli Ministry of Health to commence the Trial
- The Trial is expected to commence in the coming week, and conclude in September 2020 with results available in October 2020
- ArtemiC is classified as a food supplement, which can be produced and sold as a nutraceutical product in its current form – no new approvals or licenses are required
- MGC has the required facilities, permits and approvals to start commercial production of ArtemiC
- ArtemiC encapsulates the MyCell™ technology, a unique platform to deliver natural ingredients more effectively in higher concentrations to the cells, improving bioavailability of natural ingredients

The Trial will evaluate the safety and efficacy of the Product, and determine the claims which the product will be able to be sold as a food supplement. Importantly, MGC will own the intellectual property generated from the Trial. The results from the Trial will determine the valid claims that can be made in relation to the Product, provide data points for future trials and will be material to the commercial discussions the Company is currently undertaking with respect to potential supply and sale agreements of the Product in the short term.

Second Clinical Trial Approval Granted from leading Israeli Hospital

This is the Company's second, independent ethics committee approval granted by Hillel Yaffe Hospital, Israel which follows the Nazareth Hospital EMMS approval to conduct the Phase II placebo controlled clinical trial on patients diagnosed with COVID-19 announced on 17 April 2020. The new Phase II clinical trial approval from Hillel Yaffe Hospital is the result of the successful completion of a full ethical review undertaken by the Human Research Ethics Committee. The Phase II clinical trial will assess the safety and efficacy of the natural anti-inflammatory formulation ArtemiC, a natural supplement formula based on Artemisinin and Curcumin (along with supporting ingredients Vitamin C and *Boswellia serrata*) well-known natural active ingredients with anti-infective properties (see full detail in the ASX Announcement dated 17 April 2020).

This second site is to complement the previous Ethics Committee approval from Nazareth Hospital EMMS in Israel, by providing wider statistical data being conducted at two separate hospitals which will assist with the decision making concerning further testing to obtain the ultimate aim of achieving full marketing authorisation of ArtemiC. MGC's Clinical Advisory Team, led by Dr Jonathan Grunfeld and Dr Nadya Lisovoder, evaluated and concluded the established scientific data of known Artemisinin and Curcumin properties provide a rationale to test ArtemiC in the treatment of patients suffering from COVID-19, and a basis to undertake this further testing on ArtemiC.

Background - ArtemiC and Swiss PharmaCan AG

ArtemiC is currently designated as a food supplement, which can be produced and sold as a nutraceutical product in its current form with no new approvals or licenses required. MGC is also responsible for the necessary research, manufacture and packaging for commercial orders from its existing operational facilities in Europe, and has all the necessary approvals in place to commence commercial production, as recently announced.

As detailed in the announcement released 15 April 2020, the Company entered into a binding agreement with Micelle Technology AG ('**Micelle**'), the parent company of Swiss PharmaCan AG (together the '**Parties**'), on 4 April 2020 for MGC to provide necessary research support, commercial manufacturing and distribution of the Product, with its patented[1] MyCell Enhanced™ delivery system technology ('**MyCell™**'). This clinical trial is being undertaken pursuant to the terms of the executed binding agreement, with MGC the responsible party for the design and management of future clinical studies on the Product.

Phase II Clinical Trial Second Site - Hillel Yaffe Hospital, Israel

This second site of the Phase II clinical trial which has been approved by the Ethics Committee from Hillel Yaffe Hospital, Israel, is designed to test ArtemiC on patients infected with COVID-19 for safety and efficacy, with the purpose of treating the pathophysiological repercussions of infection with the novel coronavirus 2019 (SARS-CoV-19). The protocols for this Trial were finalised by the MGC Clinical Advisory Team, led by Dr Grunfeld and Dr Lisovoder, and provided to the Ethics Committee for approval, which has now been received. As recently announced, due to the definition of the Trial being a "Special Clinical Trial", there is no requirement for any additional approval from the Israeli Ministry of Health to commence the Trial.

The Trial is expected to commence within a week at both sites, with placement of the clinical trial insurance now complete, and is to be evaluated on a total target number of 50 patients infected with COVID-19, across the two clinical sites.

The Trial will be conducted over a period of 14 days per patient and is expected to conclude during September 2020, with results available during October 2020. Full details on the Phase II clinical trial required for compliance with the ASX Code of Best Practice for Reporting by Life Science Companies are included in Annexure A, minor updates to the selection criteria included. A successful outcome from a clinical trial will enable the Company validate claims regarding the Product, but does not necessarily guarantee regulatory approval of ArtemiC as a pharmaceutical grade product.

[1] Patent number: EP2066310A1 granted on 18 April 2012

In the event of a successful Trial on patients diagnosed with COVID-19, MGC and the Parties would make a decision based on the results for additional clinical programs on ArtemiC, with the ultimate aim to achieve full marketing authorisation through the completion of additional successful clinical trials. If the Trial is not successful, the Company would examine the results and decide at that time on the potential to proceed with further testing on ArtemiC.

Roby Zomer, Co-founder and Managing Director of MGC Pharmaceuticals, commented: "Receiving this Ethics Committee approval to proceed immediately at a second site for the Phase II clinical trial of ArtemiC is a further endorsement of the potential the Product may have in treating the pathophysiological effects of COVID-19. This trial at an additional site will evaluate the safety and efficacy of ArtemiC on patients diagnosed with COVID-19 with the aim, on receipt of successful results, to move swiftly to commercial production and sales."

"Given its classification as a nutraceutical product, and therefore requiring no further approvals or licencing, we are anticipating the ability to produce and sell ArtemiC within a short period of time following successful completion of the Trial. With our GMP certified manufacturing facilities in Slovenia remaining in operation, and with sufficient capacity to produce the Product alongside our existing medications, we are moving forward with discussions with potential partners for the global distribution of ArtemiC in anticipation of the results ensuring we have agreements in place for a potential swift route to market. We look forward to updating the market with developments of the trial progress."

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About MGC Pharma

MGC Pharmaceuticals Ltd (ASX: MXC, OTCQB: MGCLF) 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 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, 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. In order to meet the demands of becoming a key global supplier the company is constructing a large scale GMP state of the art facility in Malta.

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About Hillel Yaffe Hospital

The Hillel Yaffe Medical Center is a large hospital on the western edge of Hadera, Israel. The center is named after Hillel Yaffe, a pioneering Israeli doctor who worked in nearby Jewish settlements in the land of Palestine during the First Aliyah in the early 20th century.

The hospital carries out a wide range of academic activities. Affiliation with the Bruce Rappaport School of Medicine at the Technion in Haifa is expressed by regular educational activity for the medical students in the major clinical professions, by academic appointments for the hospital doctors and by varied research programs. Many of the departments are certified for full specialization by the Scientific Council of the Israeli Medical Association, and each year the medical centre approves new specialists in the different fields of specialization.

ANNEXURE A

Name and any unique identifier of the trial:	A Phase II, double blind placebo controlled clinical trial designed to evaluate the effect of ArtemiC in patients diagnosed with COVID-19 (ID: MOH_2020-04-16_008859)
Primary endpoint(s):	• Time to clinical improvement, defined as a national Early Warning Score 2 (NEWS2) of </= 2 Maintained for 24 Hours in comparison to routine treatment • Percentage of participants with definite or probable drug related adverse events
Secondary endpoints:	• Time until negative PCR • Proportion of participants with normalization of fever and oxygen saturation through day 14 since onset of symptoms • COVID-19 related survival • Incidence and duration of mechanical ventilation • Incidence of Intensive Care Init (ICU) stay • Duration of ICU stay • Duration of time on supplemental oxygen
Blinding status:	Double Blinded
Product status:	The Product will be packaged and labelled in compliance with Good Manufacturing Practice (GMP)
Treatment method, route, frequency, dose levels:	**Agent name and composition:** ArtemiC, medical spray composed of a combination of 6 mg/ml of Artemisinin and 20 mg/ml of Curcumin. **Dose:** Maximum dose during a day by medicated spray, divided over 2 times day. **Study Procedures:** The study will last 2 weeks and additional time required for follow up till hospital discharge in order to check side effects and study drug efficacy. **Methodology:** Safety will be assessed through collection and analysis of adverse events, blood and urine laboratory assessments and vital signs. After Screening visit, the study drug will be administrated during 2 days twice a day. All patients will be monitored till the hospital discharge.
Number of trial subjects:	Total of 50 adult patients, across both sites, who suffer from COVID-19 infection
Description of Control Group:	Placebo + Standard of Treatment
Subject selection criteria:	**Inclusion Criteria:** • Confirmed SARS-CoV-2 infection • Hospitalized COVID-19 patient in stable moderate condition (i.e., not requiring ICU admission) • Age – 18 and above • NEWS2 Score of 4 or above • Ability to receive treatment by spray into the oral cavity. • Subjects must be under observation or admitted to a controlled facility or hospital (home quarantine is not sufficient) **Exclusion Criteria:** • Tube feeding or parenteral nutrition. • Respiratory decompensation requiring mechanical ventilation • Uncontrolled diabetes type 2 • Autoimmune disease • Pregnant or lactating women • Any condition which, in the opinion of the Principal Investigator, would prevent full participation in this trial or would interfere with the evaluation of the trial endpoints.
Trial locations:	Multiple Sites in Israel – Nazareth Hospital EMMS and Hillel Yaffe Hospital
Name of the principal investigator:	Dr Ameer Elemy (Nazareth Hospital EMMS) and Dr. Jameel Mohsen (Hillel Yaffe Hospital)
Partners:	Galilee-CBR (CRO)
Expected duration:	The trial is expected to commence in the coming week and conclude around September 2020 with results then available in October 2020
Additional information:	Issues with recruitment are not expected however if this does occur could impact expected commencement date
Trial standard:	This clinical trial will be conducted in compliance with Good Clinical Practices (GCP)