28 September 2020

ASX Code: MXC

ArtemiC™ Phase II Clinical Trial Update – Trial Expanded to Rambam Hospital in Israel and MGM Hospital in India

ASX RELEASE

Key Highlights:

- Patient recruitment already commenced for Phase II Clinical Trial on COVID-19 Patients at the leading Rambam Academic Hospital in Israel, with 3 patients already enrolled for the Trial
- The interim results from the Trial met all its primary end points for the safety and efficacy of the treatment on the first 10 patients in Israel as announced on 20 August 2020 (Interim Results)
- Israel currently experiencing significantly increased COVID-19 infection rates over past 2 months
- Following the recent Interim Results received and recommendation from the medical teams at Nazareth Hospital EMMS and Hillel Yaffe Hospital in Israel, Ethics Committee approval was received from Rambam Academic Hospital in Israel
- Patient recruitment has also commenced at Mahatma Gandhi Mission's Medical College & Hospital (MGM Hospital) in India, important for patient data collection for ArtemiC™ in Asian markets
- Multiple Trial sites and geographical locations critical for EMA and FDA registration of ArtemiC™
- Currently 33 out of a total of 50 patients have been treated or recruited to participate across all sites to date, there are only 17 additional patients required to complete the Trial across Israel and India
- This double-blind placebo-controlled Phase II Clinical Trial is designed to evaluate the safety and efficacy of ArtemiC™ in patients diagnosed with COVID-19
- The Trial is expected to conclude in October with results available in November 2020

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 an update on its Phase II double-blind, placebo controlled clinical trial to evaluate the safety and efficacy of the natural anti-inflammatory formulation ArtemiC™ on patients diagnosed with COVID-19 (the '**Trial**').

Trial commences at Rambam Hospital in Israel

Patient recruitment has commenced at Rambam Academic Hospital (Rambam Hospital) with 3 patients enrolled already following receipt of Ethics Committee approval. Rambam Hospital is recognised as one of the leading medical centres in Israel. Ethics Committee approval followed the recent Interim Results received (refer ASX release 20 August 2020) and recommendation, based on the clinical experience with COVID-19 patients, from the medical teams at current trial sites Nazareth Hospital EMMS and Hillel Yaffe Hospital.

This considerably improves the Company's access to patients to complete its Trial on schedule, as Rambam Hospital is a 1,000-bed hospital serving more than two million people in Northern Israel.

Rambam is recognised as one of the leading medical centres in Israel. Providing comprehensive medical services in all medical specialties, Rambam is the tertiary referral centre for 12 district hospitals. Many of Rambam's physicians are world renowned in their clinical specialty. Physicians participate in cutting-edge research projects to bring new therapies and treatments not only to their patients, but the greater community of the world.

India Site Commencement and Trial Patient Recruitment Status

Patient recruitment has commenced at the Mahatma Gandhi Mission's Medical College & Hospital (MGM Hospital) in India with first patients expected to commence treatment within days. With 33 patients completed treatment or currently recruited across all trial sites, there are only 17 additional patients to be recruited out of the total of 50 required to complete the Trial which is on schedule to be to concluded in October with results available in November 2020.

Additional site locations outside of Israel are required for the wider statistical data required as part of the process for application of marketing authorization for ArtemiC™ with the US Food and Drug Administration (FDA) and European Medical Association (EMA) registration. Oz Innovative Solutions Pty Ltd is engaged as the local study monitor in India under the Chief Research Officer, Dr Nadya Lisovoder.

There have been 646,263 new cases of COVID-19 (in the last 7 days) reported in India as at 21 September 2020 per the World Health Organisation's (WHO) situation report taking the total COVID-19 cases in India to 5,400,619, with over 86,752 deaths to date[1].

Summary on the Trial

The trial is assessing 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, anti-inflammatory, immune-modulatory and antioxidant properties and unique delivery system that empowers the bioactivity of the ingredients.

The Company recently announced the Interim Results of the Trial met all its primary end points for the safety and efficacy of the treatment on the first 10 patients in Israel (refer ASX release 20 August 2020). Importantly, these interim results also met the FDA primary endpoint - sustained clinical recovery, the resolution of symptoms and prevented the need for intensive care or invasive mechanical ventilation. This is in accordance with FDA guidelines on the inclusion criteria for the treatment of high-risk, COVID-19 infected patients.

Expanding the trial to include India along with a third site in Israel provides MXC with the wider statistical data required as part of the process for application of marketing authorization for ArtemiC™, with the US Food and Drug Administration (FDA) and European Medical Association (EMA) registration.

The Company is currently planning a Phase IIb clinical trial to commence once this Phase II clinical trial is completed and results are analysed.

Full current details on the Phase II clinical trial required or compliance with the ASX Code of Best Practice for Reporting by Life Sciences Companies are included in Annexure A.

Roby Zomer, Co-founder and Managing Director of MGC Pharma, commented: "We are pleased to commence our clinical trial in India which will provide important wider statistical data required as part of the marketing authorization application for ArtemiC™. We are also very pleased to receive the recommendation from the medical teams from the current trial which assisted with the expansion of our clinical trial in Israel to include the Rambam Hospital. We look forward to updating the market as the trial progresses in both Israel and India."

Dr Prabhakar Ranjekar, Chief Scientific Officer, Oz Innovative Solutions Pty Ltd, commented: "We are pleased to associate with MGC Pharmaceuticals and commence recruitment of COVID-19 patients in India. Currently, India is the second most affected country by COVID-19 and a successful trial of ArtemiC™ will provide a better treatment option for the doctors. The Indian trial will also provide a good comparison on the effect of ArtemiC™ in two diverse populations."

[1] Source: WHO Situation Report COVID-19

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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 '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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Mahatma Gandhi Mission's Medical College & Hospital

MGM Hospital and medical centre research institute is a "NABH accredited" medical college hospital. It was also awarded 'Grade A' by The National Assessment and Accreditation Council (NAAC). It is a leading health care organization serving the health care needs of Marathwada region since January 1990. The hospital is centrally located in a green campus. The hospital was started with a bed strength of 50 which has now expanded to 700 sanctioned beds. The hospital provides medical and surgical services along with superspeciality services such as Cardiology, Nephrology, Plastic surgery, Neurosurgery, Urology. The hospital is supported with 85 beds of Intensive care units which includes Medical intensive care unit, surgical intensive care unit, cardiac intensive care unit, Pediatric intensive care unit, Neonatal intensive care unit etc.

The hospital is well supported with state of the art diagnostic laboratories which includes NABL accredited Central Pathology laboratory, Radiology and microbiology services. Other supportive departments include Pharmacy, Central Stores, Hygiene sanitation dept, Civil and Bio-Maintenance Dept, Security, Liquid Oxygen Plant, Laundry and linen department etc.

The hospital provides health care services through various charity schemes such as Mahatma Jotiba Phule jan Arogya Yojana, Below poverty line (BPL) Scheme, Surakshit matrutva yojana etc. As part of corporate social responsibilities it has affiliation with various corporate and non government organizations. The hospital with state of the art equipment and infrastructure and patients who come here provide very good clinical learning material to all the UG and PG students studying in the medical college.

Rambam Academic Hospital

Rambam Hospital, founded in 1938, is the largest multidisciplinary treatment and diagnostic center in the northern region of Israel. The medical center is named in honor of Rabbi Moshe ben Maimon, an outstanding Jewish philosopher, doctor, and scholar of the Middle Ages. Rambam Medical Center is a state medical institution housing 36 hospitalization departments, 45 medical and diagnostic units, 10 institutes, and 6 laboratories. The Rambam Medical Center employs a total of 4,000 employees, 715 doctors, and 1,407 nurses. About 75,000 patients undergo inpatient treatment annually, and more than 500,000 patients are on outpatient supervision by specialists from various institutions and clinics.

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; ClinicalTrials.gov Identifier NCT04382040)
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 all participant 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 patient with COVID-19 of moderate stable or worsening severity not requiring ICU admission, and on the other hand not experiencing clinical improvement under ongoing standard care. Age – 18 and 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. • Patient who need oxygen supply beyond use of nozzles or simple mask as per score 4 (Ordinal Scale for Clinical Improvement). • Respiratory decompensation requiring mechanical ventilation • Uncontrolled diabetes type 2 • Autoimmune disease • Pregnant or lactating women • Need for admission to ICU in the course of the present hospitalization at any time prior to completion of the recruitment to the study. • 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:	Three Sites in Israel – Nazareth Hospital EMMS, Hillel Yaffe Hospital and Rambam Hospital One Site in Aurangabad, India – Mahatma Gandhi Mission's Medical College & Hospital
Name of the principal investigator:	Dr Ameer Elemy (Nazareth Hospital EMMS), Dr. Jameel Mohsen (Hillel Yaffe Hospital), Dr Syed Umar Quadri (Mahatma Gandhi Mission's Medical College & Hospital), Dr. Shahad Hamud (Rambam Hospital)
Partners:	Galilee-CBR (CRO)
Expected duration:	The trial is expected to conclude in October 2020 with results available shortly after
Additional information:	If issues with patient recruitment occur, this could impact expected conclusion date
Trial standard:	This clinical trial will be conducted in compliance with Good Clinical Practices (GCP)