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ASX Code: MXC

COVID-19 Clinical Trial Update - Site expansion into India, WHO selection for research task force

ASX RELEASE

Key Highlights:

- The World Health Organisation (WHO) has established a COVID-19 taskforce and selected MGC Pharma to participate in obtaining mapping and assessment of all ongoing research
- MXC has expanded patient recruitment of its ArtemiC Phase II clinical trial on patients diagnosed with COVID-19 to the Mahatma Gandhi Mission's Medical College & Hospital in Aurangabad, India
- Full Ethics Committee approval has been received at Mahatma Gandhi Mission's Medical College & Hospital in India
- According to WHO data, there have been 18,653 people in India diagnosed with COVID-19 in the past 24 hours taking their total confirmed cases to 585,493[1]
- 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
- A successful clinical trial in India is also required for future commercial sale of ArtemiC in India
- COVID-19 infection rates have spiked sharply in Israel over the past two weeks, resulting in an increase in number of new patient applications for clinical trial participation at its two active sites at Hillel Yaffe and Nazareth Hospitals
- The trial is structured to assess the safety and efficacy of the natural anti-inflammatory formulation ArtemiC on COVID-19 infected patients and specific treatment of the cyclonic storm deterioration of the respiratory system

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 geographically expanded the recruitment of patients for 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 to India (the '**Trial**').

The Company has now expanded the clinical trial footprint to include the Mahatma Gandhi Mission's Medical College & Hospital in India, where a full ethical review has been undertaken and ethics approval has been received. 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.

The WHO is currently engaging with pharma companies globally conducting clinical trials on COVID-19 and has selected MXC to participate with its ArtemiC trial in order to obtain the latest updates and specific trial data to include them in their living systematic review. The aim is to enable decision makers to access the best current evidence on comparative effects of the interventions studied in the COVID-19 trials.

[1] Source: WHO Situation Report COVID-19

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Expanding the Phase II Clinical Trial into India

The recruitment of patients for the Phase II clinical trial in India is expected to commence mid-July 2020 for the Trial to conclude November/December 2020. The Trial expansion to India is very important for the Company as depending upon results it will facilitate the future sale of ArtemiC in India, and other Asian countries with mutual recognition with India. There have been 18,653 new cases of COVID-19 (in the last 24 hours) reported in India as at 1st July 2020 per the World Health Organisation's (WHO) daily situation report taking the total COVID-19 cases in India to 585,493, with over 17,000 deaths to date[2].

Expanding the trial to include India will also provide 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 Medicines Agency (EMA) registration.

The 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, anti-inflammatory, immune-modulatory and antioxidant properties.

Israel COVID-19 Daily Infection Rates Increasing Significantly

After a slowdown in May/June, the number of infections are increasing in Israel, in the last 24 hours there where 737 new cases - the highest per day since COVID-19 cases were initially reported Israel. Israel total cases are now over 24,000[3]. This has led to an increase in COVID-19 patient applications in recent days to participate in the Phase II Clinical trial at the Hillel Yaffe Hospital and Nazareth Hospital EMMS trial sites in Israel, which are now being assessed and processed for recruitment into the Trial.

Roby Zomer, Co-founder and Managing Director of MGC Pharma, commented: "We have expanded the patient recruitment process for our Phase II clinical trial to India where there is still a large number of new COVID-19 cases being reported on a daily basis. In addition, these wider statistical results to be obtained through the trial in India will also be required as part of the marketing authorization application for ArtemiC. We look forward to updating the market as the trial commences in India."

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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.

[2] Source: WHO Situation Report COVID-19
[3] Source: WHO Situation Report COVID-19

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.

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:	Two Sites in Israel – Nazareth Hospital EMMS, Hillel Yaffe 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) and Dr Syed Umar Quadri (Mahatma Gandhi Mission's Medical College & Hospital)
Partners:	Galilee-CBR (CRO)
Expected duration:	The trial is expected to conclude in November/December 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)