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ASX RELEASE

Ethics Committee Approval Granted for Phase III Clinical Trial of CimetrA™ on Patients Diagnosed with COVID-19

Key Highlights:

- MGC Pharma has received Ethics Committee approvals from Rambam Health Care Campus, Haifa and Nazareth Hospital EMMS in Israel, for the Phase III clinical trial to be undertaken on patients diagnosed with COVID-19 ("Trial").
- CimetrA™ is designed with the scientific aim to target viral infections with inflammatory complications and was successfully evaluated on COVID-19 (SARS-CoV-2) infected patients in a double-blind placebo controlled, Phase II clinical trial.
- MGC Pharma is fully funded to complete the Trial following the LSE IPO £6.5m raising in February 2021.
- The Trial will evaluate the efficacy and safety of CimetrA™ in the treatment of moderate hospitalised patients diagnosed with COVID-19 on a large patient group.
- The name change to CimetrA™ recognises the transfer of product under the Phase III clinical trial to an Investigational Medicinal Product ("IMP") status, while ArtemiC™ will remain as a food supplement.
- CimetrA™ encapsulates Graft Polymer's proprietary GraftBio™ SNEDDS technology (Self-Nano Emulsifying Drug Delivery System), a unique platform to deliver active ingredients more effectively in higher concentrations to the cells, improving the bioavailability of natural active ingredients.
- The Trial will provide additional data for claims on the product as an IMP and provide essential data to plan for the future regulatory pathway for the registration of CimetrA™ as a drug.
- The Trial is expected to commence in early April and conclude in September 2021, with interim results expected in June and full study results in October 2021.
- This Phase III clinical trial is currently going through regulatory approvals for additional clinical sites in Israel and Brazil.
- MGC Pharma already has the required facilities, permits and approvals to start production of CimetrA™ as an IMP.
- MGC Pharma is planning a CimetrA™ development program that will support pre-clinical and clinical trials in additional inflammatory and autoimmune indications.

MGC Pharmaceuticals Ltd (ASX, LSE: MXC, 'MGC Pharma' or 'the Company'), a European based bio-pharma company specialising in the production and development of phyto-derived medicines, is pleased to announce it has been granted Ethics Committee approval from Rambam Health Care Campus and Nazareth Hospital EMMS in Israel, to conduct a Phase III Clinical Trial (the **Trial**) to evaluate the efficacy and safety of CimetrA™ as a treatment for moderate hospitalised patients diagnosed with COVID-19 and to provide additional data for claims on the product as an IMP. The Trial is now scheduled to commence in early April, and will provide essential data to plan for the potential future registration of CimetrA™ as a drug.

Under the move to a Phase III clinical trial, the classification of the product has changed from a food supplement to an IMP. As a result, the product name under the Trial has changed from ArtemiC™ to CimetrA™. ArtemiC™ will remain as a food supplement and available under the master distribution agreement with Swiss Pharmacann, while CimetrA™ becomes an IMP which will include changing the drug carrier to a new polymeric drug carrier GraftBio™ (SNEDD – Self Nano Drug Delivery), with a view to potentially being registered as a drug in the future.

Phase III Clinical Trial Approval Granted from two Israeli Hospitals

The Company has received two independent Ethics Committee approvals granted by Rambam and EMMS Hospitals in Israel to conduct the Phase III placebo controlled clinical trial on patients diagnosed with COVID-19. The Phase III clinical trial approvals from Rambam and EMMS Hospitals is the result of the successful completion of a full ethical review undertaken by the respective Human Research Ethics Committees following the successful completion of the Phase II trial announced on 15 December 2020.

Rambam Health Care Campus is a 1000-bed world-class Governmental teaching hospital. The patient population is diverse, as Rambam is the major tertiary (referral) medical centre for all of Northern Israel serving more than two million residents and others referred from all over Israel, the Mediterranean region, and around the world.

The Nazareth Hospital EMMS is one of the oldest hospitals in the Middle East, and the largest in Nazareth. EMMS is a general hospital with Nazareth's main Emergency Room that works 24/7, ICU, a recently refurbished Cath Lab, Orthopaedic Surgical department, General Surgical department, Pediatric surgical unit, Urology Unit and Esthetic Clinic. The hospital has a Medical department with Tuberculosis and Cardiac clinics, as well as a Dialysis unit, Psychiatry Department, Delivery rooms, a unique Neonate unit, Gastrology unit, X-ray department and other medical clinics that serve tens of thousands of patients every year.

Phase III Clinical Trial

The Phase III clinical trial which has been approved by the Ethics Committee from Rambam and EMMS Hospitals, Israel, is designed to test CimetrA™ on moderate hospitalised 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 Phase III clinical trial will assess the efficacy and safety of the natural anti-inflammatory formulation CimetrA™, based on Curcumin and Boswellia Serrata as Anti-inflammatory agents with the supporting ingredient Artemisinin as an Antiseptic peroxide bridge, which are all well-known natural active ingredients with immunomodulatory properties (see full detail in ASX Announcement 17 April 2020).

The protocols for this Trial were finalized by the MGC Pharma 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 in early April, with placement of the clinical trial insurance now complete, and is to be evaluated on a total target number of 252 patients infected with COVID-19, across clinical sites in Israel and Brazil. The interim Trial results are expected to be received and published by June 2021.

The Trial will be conducted over a period of 28 days per patient and is expected to conclude during September 2021, with results available during October 2021. Full details on the Phase III clinical trial required for compliance with the ASX Code of Best Practice for Reporting by Life Science Companies are included in Annexure A, with minor updates to the selection criteria included.

Roby Zomer, Co-founder and Managing Director of MGC Pharma, commented: "This is a very significant milestone for the Company being the first Phase III clinical trial of CimetrA™. ArtemiC™ has already proven to be a very successful product for the Company, and we look forward to replicating this with CimetrA™ as an IMP and improve outcomes for COVID-19 patients."

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About MGC Pharma

MGC Pharmaceuticals Ltd (LSE: MXC, 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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About CimetrA™

CimetrA™ is an IMP, currently undergoing Stage III clinical trials in Israel and Brazil for the treatment of COVID-19. It contains three natural based ingredients consisting of Curcumin, Boswellia serrata, and Artemisinin capsulated in GraftBio™ SNEDDS. CimetrA™ product name has changed and drug delivery system from ArtemiC™ as a result of it becoming an IMP instead of a food supplement. CimetrA™' s clinical trial is expected to be completed in September 2021, with the findings available in October 2021.

MGC is planning to develop a preclinical and clinical programs for other indications for CimetrA use. An anfti inflammatory effect of CimetrA can be used in a wide spectrum of inflammatory and autoimmune diseases, like IBD, RA, flue, pneumonia and others.

ANNEXURE A

Name and any unique identifier of the trial:	A Phase III, double-blind, controlled clinical study designed to evaluate the effect of CimetrA™ in patients diagnosed with COVID-19 ("Trial")
Primary endpoint(s):	Time to sustained clinical improvement, defined as a national Early Warning Score 2 (NEWS2) of ⍰ 2 Maintained for 24 Hours in comparison to routine treatment (measured on days 7, 14, 28)
Secondary endpoints:	• Number of participants with depending on oxygen supplementation through day 28 since onset of symptoms • Change in inflammatory marker levels – IL-6, IL-1β, IL-12, TNF α, IFN-γ, CRP, NLR (Neutrophil / Lymphocyte ratio) at days 1, 2, 4, 7, compared to baseline • Pharmacokinetic profile of the study drug • Incidence and duration of mechanical ventilation • Incidence of Intensive Care Unit (ICU) stay during COVID-19 complication • Percentage of participants with definite or probable drug related adverse events • Long-term adverse events of COVID-19 on Day 28 • Quality of life of patients on Days 0, 14 and 28. • The exploratory outcomes: • Course of change in D Dimer levels compared to baseline • Occurrence of secondary infections
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:	Study Product – Arm 1: CimetrA-1, with a total dose containing a combination of Artemisinin 12 mg, Curcumin 40 mg, Boswellia 30 mg and Vitamin C 120 mg in spray administration – divided in 4 separate doses given as an add on therapy, 4 doses over 48 hours (day 1 and day 2), twice a day (morning and evening). Arm 2: Placebo, composed of the same solvent but without active ingredients, given as an add on therapy in spray administration, 4 doses over 48 hours (day 1 and day 2), twice a day (morning and evening). Study Procedures: The study will last 4 weeks and additional time required for follow up till hospital discharge in order to check side effects and study drug efficacy. Methodology: Multi-centre multinational-controlled study. 252 adult patients who suffer from moderate COVID-19 infection. 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 twice a day morning and evening (every 12 hours) during (day 1 and day 2) The patients will be randomized in 1:1 ratio to study drug (CimetrA™) in addition to Standard of Care (Arm 1) or to Placebo in addition to Standard of Care (Arm 3).
Number of trial subjects:	Total of 252 adult patients, across Israel and Brazil, who suffer from COVID-19 infection
Description of Control Group:	Placebo + Standard of Treatment

Subject selection criteria:	**Inclusion Criteria:** • Confirmed SARS-CoV-2 infection • Hospitalised 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 and Brazil
Name of the principal investigator:	Dr Ameer Elemy (Nazareth Hospital EMMS) Dr. Shadi Hamoud
Partners:	Galilee-CBR (CRO)
Expected duration:	The Trial is expected to commence in the coming week and conclude around September 2021 with results then available in October 2021
Additional information:	Not applicable.
Trial standard:	This clinical trial will be conducted in compliance with Good Clinical Practices (GCP)