8 July 2022

ASX Code: MXC

LSE Code: MXC

ASX RELEASE

South African Ethics Committee Approval Granted for the Dose Finding Study of CimetrA™ on Patients Diagnosed with COVID-19

Key Highlights:

- MGC Pharma has received Study approvals and an Import Permit from the South African Health Products Regulatory Authority for MGC Pharma's Phase IIb CimetrA™ dose finding study on patients diagnosed with COVID-19.
- **CimetrA™** is designed with the scientific aim of targeting the effects of viral infections with associated inflammatory complications and successfully demonstrated it immunomodulatory and anti-inflammatory effects on patients with moderate COVID-19, in a double-blind placebo controlled, Phase II clinical trial (as announced 28 September 2020)
- The study aims to determine the most effective dosage concentrations of the active ingredients, as well as collecting data to further validate **CimetrA™**'s anti-inflammatory and immune-modulatory effects.
- The Trial will provide additional data for claims on the product as an Investigational Medical Product ("IMP") and provide essential data to plan the future regulatory pathway for the registration of **CimetrA™** as a drug.
- The South African study site adds to the existing site at Rambam Medical Center, Haifa, Israel, which has been recruiting patients since 2021, with interim analysis results expected in the coming weeks.
- **CimetrA™** is a nanoparticle micellar formulation based on the pharmaceutical synergetic composition consisting of Curcumin and Boswellia. **CimetrA™** has demonstrated anti-inflammatory and immunomodulating effects and can be designed for multiple therapeutic applications utilising Graft Polymer IP Ltd's (Graft Polymer) proprietary GraftBio™ Self-nano-emulsifying Drug Delivery System.
- MGC Pharma is also collecting data related to Long COVID, one of the main complications of the disease, with findings to be released shortly.
- Based on the recently released results from MGC Pharma's pre-clinical study to determine the mechanism of action of **CimetrA™**, MGC Pharma is planning to develop a clinical program for other inflammatory indications to determine the efficacy of **CimetrA™** on these conditions. Results from the pre-clinical study indicate that the anti-inflammatory effects of **CimetrA™** may be efficacious in a wide spectrum of inflammatory and autoimmune diseases, such as IBD, RA, Influenza, and dermatological diseases, among others.

MGC Pharmaceuticals Ltd ('MGC Pharma' or 'the Company') a European based bio-pharma company specialising in the production and development of phytomedicines, has received study and importation approval from the South African Health Products Regulatory Authority for the Phase IIb dose finding study to be undertaken on patients diagnosed with COVID-19 ("Trial").

The study to be undertaken in South Africa is an extension of the dosing study currently underway in Israel (See announcement 2 November 2021), with interim analysis results due in the coming weeks.

The Trial will incorporate key parameters, which include determining the most effective dosage of the treatment, a full safety and Pharmacovigilance profile, and an extensive Pharmacokinetic profile of **CimetrA™** to outline the registration and administrative process for approval for sale and use. The Trial will further examine the anti-inflammatory and immune-modulatory effects of **CimetrA™** through Cytokine level monitoring.

The establishment of the South African trial site will help to accelerate completion of the ongoing study, and the collection of data necessary for the submission of **CimetrA™** with regulators internationally, which the Company views as a priority, particularly at a time when cases of COVID-19 are once again on the rise.

Recent studies of **CimetrA™** have indicated the mechanism of the drug could be effective in treating other conditions where a primary factor is inflammation. These include autoimmune diseases Irritable Bowel Disease, Rheumatoid arthritis, Influenza, and dermatological diseases, amongst others.

Roby Zomer, co-founder and Managing Director of MGC Pharmaceuticals, commented: "With COVID-19 cases once again on the rise, the extension of the **CimetrA™** dosage trial into South Africa could not be more important.

Clinical trials to date have demonstrated the efficacy of **CimetrA™** against COVID-19, so it is crucial that we are able to complete the dosage trials in Israel and now South Africa as quickly as possible so we can move to the next stage of the clinical pipeline and treat those suffering from the effects of the cytokine storm and "Long COVID" more effectively."

--Ends--

Authorised for release by the Managing Director, for further information please contact:

MGC Pharmaceuticals Ltd
Roby Zomer
CEO & Managing Director
+61 8 6382 3390
info@mgcpharma.com.au

MGC Pharmaceuticals Ltd
David Lim
Company Secretary
+61 8 6382 3390
info@mgcpharma.com.au

UK Broker – Turner Pope
Andy Thacker
+44 203 657 0050
info@turnerpope.com

UK PR Advisors – Tavistock
Charles Vivian /Tim Pearson
+44 207 920 3150
mgcpharma@tavistock.co.uk

About MGC Pharma

MGC Pharmaceuticals Ltd (LSE: MXC, ASX: MXC) is a European based bio-pharma company developing and supplying affordable standardised phytomedicines 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.

Follow us through our social media channels

ANNEXURE A

Name and any unique identifier of the trial:	A Phase IIb, double blind, placebo-controlled clinical study designed to evaluate the effect of CimetrA in patients diagnosed with COVID-19 ("Trial")
Primary endpoint(s):	Efficacy endpoint: - Change in WHO Ordinal Scale for clinical improvement (measured on days 1, 7, 14, 28) - Change in COVID-19-Related Symptoms score (measured on days 1,7, 14, 28) Safety endpoint: Will be assessed through collection and analysis of adverse events, blood and urine laboratory assessments and vital signs.
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:	<u>Study Product –</u> Arm 1: CimetrA-1, with a total dose containing a combination of 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, total of 4 doses over 48 hours (day 1 and day 2), twice a day (morning and evening). Arm 2: CimetrA-2, with a total dose containing a combination of Curcumin 28 mg, Boswellia 21 mg and Vitamin C 84 mg in spray administration – divided in 4 separate doses given as an add on therapy, total of 4 doses over 48 hours (day 1 and day 2), twice a day (morning and evening). Arm 3: Placebo, composed of the same solvent but without active ingredients, given as an add on therapy in spray administration,

	total of 4 doses over 48 hours (day 1 and day 2), twice a day (morning and evening). Patients will be randomized in 1:1:1 ratio to one of the three arms. 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. 240 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)
Number of trial subjects:	Total of 240 adult patients, across Israel and S. Africa, who suffer from COVID-19 infection
Description of Control Group:	Placebo + Standard of Treatment
Subject selection criteria:	**Inclusion Criteria:** 1. Confirmed by PCR test SARS-CoV-2 infection (according to nationally authorized laboratory criteria) 2. Hospitalized patient with COVID-19 of moderate stable or worsening severity not requiring ICU admission (Moderate defined by NIH criteria -as fever, cough, dyspnea, fast breathing, but no signs of severe pneumonia, including SpO2 ≥ 94% on room air). 3. Age: 18 years old and above. 4. Subjects must be hospitalized 5. Ability to receive treatment by spray into the oral cavity **Exclusion Criteria:** 1. Tube feeding or parenteral nutrition. 2. Patients with scores 5 or above per the Ordinal Scale for Clinical Improvement published by the WHO. (i.e., who need oxygen supply beyond use of nozzles or simple mask) 3. Need for admission to ICU during the present hospitalization at any time prior to completion of the recruitment to the study. 4. 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 S. Africa
Partners:	Galilee-CBR (CRO)
Expected duration:	The Trial is expected to commence in the coming week and conclude around October 2022 with results then available in November 2022
Additional information:	Not applicable.
Trial standard:	This clinical trial will be conducted in compliance with Good Clinical Practices (GCP)