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ASX RELEASE

# Interim Results - CimetrA™ Dose Finding Study

**Key Highlights:**

- The interim results from the 16 patients using **CimetrA™** demonstrated no significant COVID-19 related complications, compared to 62.5% of the placebo group.
- Improvement was also observed in trial participants with COVID-19 taking **CimetrA™** in a number of parameters measuring the clinical condition of the participants, mainly in respiratory rate and oxygen saturation, the most important symptoms of COVID-19.
- The study, as announced in November 2021, will be used to determine the most effective concentrations of the active ingredients for dosage, as well as further validating the anti-inflammatory and immune-modulatory effects of **CimetrA™**.
- The ongoing study which is scheduled to enrol 240 patients is currently underway at the Rambam Medical Centre in Israel, with the Company planning to open additional sites globally.
- Completion of the dosage study is the next phase in moving **CimetrA™** towards marketing authorisation as a registered medicine.
- **CimetrA™** to undergo a full safety and pharmacokinetic profile to support the administration route as a part of the registration process.

**MGC Pharmaceuticals Ltd ('MGC Pharma'** or **'the Company'),** a European based bio-pharma company specialising in the development and production of medicines, is pleased to announce interim results from the data collected from the initial 16 patients participating in the **CimetrA™** dose finding study, which is underway to determine the most effective concentrations of active ingredients for dosage, as well as further validate the anti-inflammatory and immune-modulatory effects of the treatment.

The data collected from the 16 patients with COVID-19 who have completed the Clinical Trial treatment program show that 62.5% of patients in the placebo group reported adverse events related to the symptoms of COVID-19, with no patients from both drug study groups demonstrating any COVID-19 related adverse events.

Results have also shown improvements in multiple parameters measuring the clinical condition of the patient including respiratory rate and oxygen saturation, both of which showed a vector of improvement against the placebo.

Whilst the sample size on which the interim analysis has been performed is small and cannot be used for Inferential statistical analysis, the results thus far are very encouraging and in line with the Company's expectations.

The full study, which is ongoing, incorporates key parameters including determining the most effective dosage of the treatment, a full safety and Pharmacovigilance profile, in addition to an extensive Pharmacokinetic profile to outline the registration and administrative process of approval for sale and use. The study aims to further examine the anti-inflammatory and immune-modulatory effects of **CimetrA™** through Cytokine level monitoring.

There are currently a further 24 patients actively participating in the study being carried out at the Rambam Medical Centre in Israel.

The Clinical Trial Study Protocol can be found in the accompanying Annexure A.

**About CimetrA™**

**CimetrA™** is a nanoparticle micellar formulation based on the pharmaceutical synergetic composition consisting of Curcumin and Boswellia. In clinical trials **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.

Preclinical and clinical results to date have demonstrated **CimetrA™**'s mechanism of action as an anti-inflammatory and immunomodulatory agent which is effective in the prevention of severe inflammation by its control of increased Cytokine production resulting from an infection of the different variants of SARS-CoV-2 (the virus responsible for COVID-19); and which is the forerunner of a Cytokine Storm, which is believed to be the main reason for mortality in severe COVID-19 patients.

**--Ends--**

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## About MGC Pharma

MGC Pharmaceuticals Ltd (LSE: MXC, ASX: MXC) is a European based bio-pharma company, focused on developing and supplying affordable (Accessible) and Ethically Produced Plant Inspired Medicines, which combining Inhouse Research with Innovative technologies, with the goal to find treatments to Unmet medical conditions.

The Company's founders and executives are key figures in the global pharmaceuticals industry and the core business strategy is to develop and supply high quality plant inspired medicines for the growing demand in the medical markets in Europe, North America and Australasia.

MGC Pharma has a robust development pipeline targeting two widespread medical conditions – epilepsy and dementia – and has further products under development. Employing its 'Nature to Medicine' strategy, MGC Pharma has partnered with renowned institutions and academia to optimise the development of targeted plant inspired medicines, to be produced in the Company's EU-GMP Certified manufacturing facilities.

MGC Pharma has a number of research collaborations with world renowned academic institutions, recent research highlights include the potential impact of using specific 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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## Annexure A

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| **Protocol Title** | A Phase IIb, double blind, placebo-controlled clinical study designed to evaluate the effect of CimetrA in patients diagnosed with COVID-19 |
| **Study Arms** | STUDY DRUG – CIMETRA will be administrated as the following:<br>Arm 1: CimetrA-1, with a total dose containing a combination of Curcuma longa rhizomedry extract 28 mg, Boswellia serrata resin dry extract 60 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).<br>Arm 2: CimetrA-2, with a total dose containing a combination Curcuma longa rhizome dryextract 19.6 mg, Boswellia serrata resin dry extract 42 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).<br>Arm 3: Placebo, composed of the same solvent but without active ingredients, given as anadd on therapy in spray administration, total of 4 doses over 48 hours (day 1 and day 2), twice a day (morning and evening).<br>Patients will be randomized in 1:1:1 ratio to one of the three arms. |
| **Study Purpose** | This study designed to evaluate the efficacy, pharmacokinetic parameters, and safety of CimetrA on patients diagnosed with COVID-19. |
| **Methodology and study procedures** | • Multi-center multinational-controlled study in Israel, Russia, South-Africa and the United States.<br>• 240 adult patients who suffer from moderate COVID-19 infection.<br>• Safety will be assessed through collection and analysis of adverse events, blood and urine laboratory assessments and vital signs.<br>• After Screening visit, the study drug will be administrated twice a day morning and evening (every 12 hours) during (day 1 and day 2)<br>• The patients will be randomized in 1:1:1 ratio to study drug (CimetrA) in two dosages in addition to Standard of Care - Arm 1, 2 or (Placebo) in addition to Standard of Care- Arm 3. |
| **Study Duration** | Study will take place during patient's hospitalisation due to COVID-19 infection. The study will last up to 4 weeks, until conclusion on day 28. In case of hospital discharge within the study period, follow up will continue per protocol until day 28 wherever the subject will be located, performed via phone call or in-clinic, depending on the status of the patient and study schedule. |
| **Study Endpoints** | The primary outcomes:<br>Efficacy endpoint:<br>- Change in WHO Ordinal Scale for clinical improvement (measured on days 1, 7, 14, 28)<br>- Change in COVID-19-Related Symptoms score (measured on days 1,7, 14, 28)<br>Safety endpoint: will be assessed through collection and analysis of adverse events, blood and urine laboratory assessments and vital signs.<br>The secondary outcomes:<br>• Number of participants with depending on oxygen supplementation through day 28 since onset of symptoms<br>• 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<br>• Pharmacokinetic profile of the study drug on day 1 through 24 Hrs.<br>• Incidence and duration of mechanical ventilation<br>• Incidence of Intensive Care Unit (ICU) stay during COVID-19 complication<br>• Percentage of participants with definite or probable drug related adverse events |

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| | • Long term adverse events of COVID-19 on Day 28<br>• The impact of COVID-19 on quality of life of patients on Days 1, 14 and 28.<br>The exploratory outcomes:<br>• Course of change in D Dimer levels compared to baseline<br>• Occurrence of secondary infections |