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ASX RELEASE

# Approval For Global CimetrA™ Dose Finding Study

**Key Highlights:**

- A dose finding study for MGC Pharma's proprietary treatment of COVID-19 infected patients, **CimetrA™**, has been approved by the Rambam Medical Center's Ethics Committee in Israel
- The study will determine and define the most effective concentrations of the active ingredients for dosage, as well as further validating the anti-inflammatory and immune-modulatory effects of **CimetrA™**
- **CimetrA™** will undergo a full safety and Pharmacokinetic profile to support the administration route as a part of the registration process
- 240 patients to be recruited to the study across Israel, the USA, South Africa, and Russia
- The study includes a 28-day observational period in order to exclude long term complications of COVID-19, such as long COVID and post-COVID, from the study
- Completion of the dosage study is the next phase in moving **CimetrA™** towards marketing authorisation as a registered medicine

**MGC Pharmaceuticals Ltd ('MGC Pharma'** or **'the Company'),** a European based bio-pharma company specialising in the development and production of phytomedicines, is pleased to announce that the Israeli Ministry of Health has approved the Dosing Study for **CimetrA™**, MGC Pharma's proprietary treatment for the effects of COVID-19.

The Study will incorporate 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 will further examine the anti-inflammatory and immune-modulatory effects of **CimetrA™** through Cytokine level monitoring.

MGC Pharma will recruit 240 patients into the Study in sites located in Israel, South Africa, the USA, and Russia, and will continue to observe patients enrolled in the trial for the 28 day follow up period in order to ensure that data is not impacted by the effects of either long or post-COVID. The results will be submitted to the health authorities of Israel, the USA, South Africa, and Russia.

The results of this dosing study will enable MGC Pharma to determine the most effective dosage of **CimetrA™** for treating the symptoms of COVID-19 including the Cytokine Storm. The results of this Study will be used to provide additional evidence to regualtory authorities around the world about **CimetrA™'**s efficacy.

**About CimetrA™**

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

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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 which results 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.

The safety profile of **CimetrA™** has been demonstrated during a number of *in vitro* and *in vivo* clinical trials undertaken in a GLP (Good Laboratory Practice) Accredited lab operated by Science in Action, a boutique preclinical contract research organisation located in Israel. These findings are further supported by the Phase II Clinical Trial undertaken by MGC Pharma in 2020, which demonstrated a full safety profile for **CimetrA™**.

MGC Pharma have recently gained approval to import samples of **CimetrA™** into India by the Indian Central Drugs Standard Organisation in order to facilitate final product testing required for the grant of Emergency Use Authorisation for the treatment of patients with COVID-19. As part of this process, an observational trial has shown for the first time the efficacy of **CimetrA™** in the treatment of patients with *severe* COVID-19.

Roby Zomer, Co-founder and Managing Director of MGC Pharma, commented: "This latest dosage study is the latest step as we move closer to being in a position to apply for marketing authorisation for **CimetrA™** in territories across the globe.

We believe that **CimetrA™** will prove to be a vitally important drug in the treatment of COVID-19 going forward, and look forward to sharing the results of the study in due course, along with further steps towards providing COVID-19 patients and Governments across the world a cost effective treatment to fast track patient recovery and minimise the massive cost burden of long term hospitalisation."

**--Ends--**

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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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## 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 |