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ASX RELEASE

CimetrA™ import approval granted in India for Emergency Use Authorisation registration

Key Highlights:

- MGC Pharma has been granted government approval to import its phytomedicine **CimetrA™** into India as a final step towards obtaining Emergency Use Authorisation for the treatment of patients with COVID-19.
- Emergency Use Authorisation is the registration process for medicines approved for the treatment of COVID-19 around the world.
- Emergency Use Authorisation would enable MGC Pharma to market and sell **CimetrA™** as an approved medicine for the treatment of COVID-19 in India, and potentially in other territories under international Mutual Recognition protocols for medicines.
- Medopharm Private Ltd (**Medopharm**), one of the leading manufacturers and exporters of pharmaceutical products in India, is managing the Emergency Use Authorisation process for **CimetrA™** in India on MGC Pharma's behalf.
- Medopharm has been appointed importer for **CimetrA™** in India once the Emergency Use Authorisation has been granted
- **CimetrA™** is currently undergoing Phase III trial for the treatment of COVID-19 l in Israel

MGC Pharmaceuticals Ltd ('MGC Pharma' or **'the Company'),** a European based bio-pharma company specialising in the production and development of phytomedicines, has been granted a permit to import **CimetrA™** into India by the Indian Central Drugs Standard Control Organisation (**CDSCO**) to facilitate final product testing to complete its application for Emergency Use Authorisation to treat patients with COVID-19.

The application for Emergency Use Authorisation by CDSCO has been co-ordinated by P.T.K. Consulting Ltd (**PTK**), an Israeli consulting company operating in the fields of Medicine, Medical technology, and Pharmaceuticals. Medopharm, one of the leading manufacturers of pharmaceutical products in India, has been appointed to import and market **CimetrA™** in India.

The Emergency Use Authorisation allows local regulators to help strengthen the nation's public health protections against chemical, biological and other threats including infectious diseases, by facilitating the availability and use of medical countermeasures needed during public health emergencies.

Medopharm has over 50 years of experience of in-house development and licensing of medicinal products and will use this experience to manage the Marketing Authorisation approval process for **CimetrA™** in India, on behalf of MGC Pharma.

MGC Pharma has secured this import license from CDSCO for **CimetrA™** to enable it to submit final samples of **CimetrA™** for testing and analysis. If the tests are successful, the temporary import approval will be converted to a permanent approval once **CimetrA™** has been registered as a

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medicine in India under the Emergency Use Authorisation Protocols. The process is expected to take 90 days from the import of the **CimetrA™** samples into India.

To meet the potential significant increase in demand for **CimetrA™** as the result of Emergency Use Authorisation in India, MGC has secured agreements with two additional EU GMP certified production facilities which can be used to manufacture large commercial quantities of **CimetrA™** until the Company's Malta production facility completes its commissioning and is fully operational in 2022.

About CimetrA™

CimetrA™ is a nanoparticle micellar formulation based on the pharmaceutical synergetic composition consisting of Curcumin and Boswellia. CimetrA™ has anti-inflammatory and immuno-modulating effects, and can be designed for multiple therapeutic applications, utilising self-nanoemulsifying drug delivery systems.

Preclinical and Clinical results to date have demonstrated **CimetrA™**'s mechanism of action as an anti-inflammatory and immunomodulatory agent effective in the prevention of severe inflammation by control of the increased cytokine production, found in different variants and mutations of COVID-19; the forerunner of cytokine storm, believed to be the main reason for mortality in severe COVID-19 patients.

CimetrA™ is currently undergoing a Phase III clinical trial in Israel as an Investigational Medicinal Product for the treatment of COVID-19 following successful Phase II trials in 2020. The first patient was enrolled in the trial in July 2021.

Roby Zomer, Co-founder and Managing Director of MGC Pharma, commented: "We are pleased to have secured a license to import CimetrA™ as an Emergency Use Drug in India, and hope that we can secure approval swiftly to expand its availability to a much wider patient base.

"India has been acutely affected by the COVID-19 pandemic and we believe that CimetrA™ can make an important difference in treating the symptoms of COVID-19 and alleviate patient suffering. It is important that we have secured Medopharm, as the importer and the marketing authorisation holder of CimetrA™ given their vast experience of taking medicinal products through the process to full approval for sale."

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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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