

7 December 2022 ASX Code: MXC LSE Code: MXC

## Completion of CimetrA™ Efficacy Pre-clinical Trial

## **Key Highlights:**

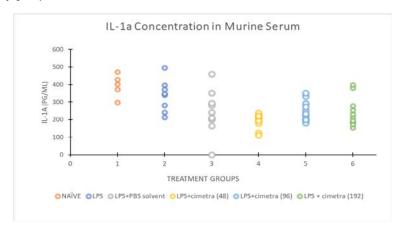
- A pre-clinical study has now been completed on a model of cytokine storm in rodents using the CimetrA<sup>TM</sup> formulation, and has demonstrated an anti-inflammatory effect in three different dosages of treatments.
- The study results demonstrate CimetrA<sup>TM</sup>'s effect on the anti-inflammatory and pro-inflammatory cytokines and chemokines which support the previous anti-inflammatory results of CimetrA<sup>TM</sup>.
- The study results will form part of the US Food and Drug Administration (FDA) application to register CimetrA™ as an Investigational New Drug (IND), and is a critical milestone in the process of drug registration.

MGC Pharmaceuticals Ltd ('MGC Pharma' or 'the Company'), a European based pharmaceutical company specialising in the production and development of plant inspired medicines, has completed pre-clinical trial testing the efficacy of the CimetrA™ formulation on rodents exhibiting the cytokine storm, in order to measure the anti-inflammatory effects of three different dosages.

The trial, carried out at the GLP-certified Science in Action Laboratory in Ness Ziona, Israel, demonstrated the anti-inflammatory effect of the treatment, with the histopathology showing the reduction of lung inflammation resulting from the onset of a cytokine storm<sup>1</sup>, in comparison to the control group. This was measured through the relative protein concentration of the cellular and acellular concentrations of the lung system.

This study is the next step in the regulatory process for Investigational New Drug (IND) approval, and is one of a cohort of studies needed to evaluate safety and efficacy in preclinical and clinical models. An IND application is expected to be submitted Q1 2023 for CimetrA™, as set out in prior company releases.

Through these studies, CimetrA<sup>TM</sup> has been shown to reduce the production of Interleukin  $1\alpha$  (IL- $1\alpha$ ), an inflammatory cytokine responsible for activating the escalation of disease manifested in the form of severe acute or chronic inflammation. Study groups included Naïve, LPS, LPS solvent PBS, LPS+CimetrA<sup>TM</sup> 48 µg, LPS+CimetrA<sup>TM</sup> 96 µg, LPS+CimetrA<sup>TM</sup> 192 µg. The graph displaying the results for each study group, control and treatment, is shown below:



<sup>&</sup>lt;sup>1</sup> Cytokine Storm: A severe immune overreaction in which the body releases higher than normal levels of inflammatory cytokines into the blood too quickly

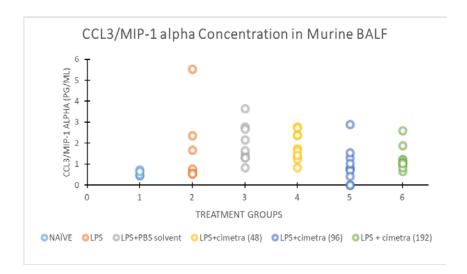
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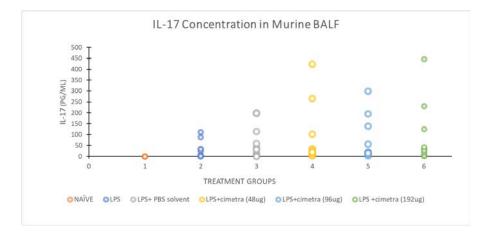
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Secondary test work illustrated the effect of CimetrA<sup>TM</sup> on the Macrophage inflammatory protein-1 alpha (MIP- $1\alpha$ /CCL3), which is a chemotactic chemokine secreted by macrophages – the white blood cells that stimulate the body's immune system. The protein performs various biological functions, such as recruiting inflammatory cells, wound healing, inhibition of stem cells, and maintaining effector immune response.



IL-17 has anti-inflammatory activity and this cytokine can suppress the development of autoimmune and inflammatory disease.



The study was completed on 55 rodents and the results presented efficacy results are statistically significant (p<0.05). This model demonstrates the anti-inflammatory mechanism of action of CimetrA<sup>TM</sup> and will support the future definition of the clinical program, based on the cytokines that were affected by the drug.

Roby Zomer, co-founder and Managing Director of MGC Pharmaceuticals, commented: "The completion of this study is critical in the advancement of our submission to the FDA and for the final approval of CimetrA $^{TM}$  as an IND in the US. There are further efficacy and safety trials to support our application, but these results are key step in the demonstration of CimetrA $^{TM}$  as a treatment for the symptoms of the cytokine storm."



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

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## About MGC Pharma

MGC Pharmaceuticals Ltd (LSE: MXC, ASX: MXC) is a European based pharmaceuticals company, focused on developing and supplying accessible and ethically produced plant inspired medicines, combining in-house research with innovative technologies, with the goal of finding or producing treatments to for 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 and has further products under development.

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 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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