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Positive Pre-clinical Trial Results on CimetrA®

ASX RELEASE

Key Highlights:

- Successful completion of Pre-clinical Chronic Toxicology Evaluation of CimetrA® delivers positive results, supporting previous pre-clinical and clinical data.
- Study demonstrated full chronic safety and toxicology profile of CimetrA® in large animals was found to be totally safe.
- Trials performed under animal EC approval in the GLP certified Lab Science in Action, Ness Ziona, Israel.
- Study is an important step in the IND submission preparation for the FDA and was designed and managed according to industry guidelines.

MGC Pharmaceuticals Ltd ('**MGC Pharma'** or '**the Company**') a European based pharmaceutical company specialising in the production and development of plant derived medicines, is pleased to announce positive pre-clinical trial results from the recently completed Pre-clinical Chronic Toxicology Evaluation of 14 days oral dose of CimetrA®.

The recently completed study was undertaken on 32 domestic swine, that received a study treatment (three dosages groups of CimetrA® and Placebo) for 14 days. During this period, the clinical parameters were recorded, blood (hematology, coagulation and chemistry) and urine tests were collected and sent to the histopathological evaluation.

The study demonstrated that following the full chronic safety and toxicology analysis of CimetrA® in large animals – the drug was found to be safe. The histopathological analysis of the full organs spectrum demonstrated all tissues of all animals were normal and unaffected. It was concluded that the test article at the dosage administered did not induce toxicological changes. No changes in the blood and urine samples were reported.

The study was performed under animal EC approval in the GLP certified Lab Science in Action, Ness Ziona, Israel, and is an important step in the Investigational New Drug ("IND") submission preparation for the US Food and Drug Administration ("FDA"). The study was designed and managed according to industry guidelines and the IND submission is planned for Q1 2024.

Roby Zomer, CEO and Managing Director of MGC Pharmaceuticals, commented: "We are delighted with the positive clinical trial results for CimetrA® which paves the way for our IND submission to the FDA next year. The potential addressable market for our anti-inflammatory and immunomodulating product is considerable and this represents a key milestone for the business."

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 MGC and 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 may be effective in the prevention of severe inflammation by its control of increased Cytokine production resulting from an infection of the 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 pharmaceutical company, focused on developing and supplying accessible and ethically produced plant derived 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 derived 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 derived 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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ANNEXURE A

The CimetrA® large animal study was performed in the Science in Action Laboratory in Ness Ziona, Israel, under Ethics Committee Approval Number AHMC-IL-2302-106-2.

Science in Action is accredited for OECD principles of Good Laboratory Practice ENV/MC/CHEM (98)17 for toxicity studies; however, this study does not follow the complete GLP regulations, and is thus considered a non-GLP study. The study follows this protocol and the Science in Action SOPs. The FDA does not require GLP for safety in vivo. As it is not mandatory to be under GLP therefore it was decided there was no clinical or regulatory reason to do GLP on this study.

The objective of the study was to determine the chronic toxicological effect of oral dose (spray twice a day) of CimetrA® over 14 days in swine. The study included 32 domestic swine (16 males and 16 females). Each animal was administered with the CimetrA spray twice daily according to dosing formulations groups listed below. At termination (14 days ±2 days), a necropsy consisting of examination and collection of relevant tissue/organs was performed. Relevant tissue/organs samples were processed for histopathology evaluation.

Study groups -

Group	**Dosage (per pig)**	**(Males/Females)**
Vehicle	Vehicle - twice a day	4/4
Low Dose	1.4mg/3mg - twice a day	4/4
Mid Dose	2.8mg/6mg - twice a day	4/4
High Dose	5.6mg/12mg - twice a day	4/4

Hematology, coagulation and chemistry blood tests were collected during the study. In the study termination, organs (Brain (cerebrum), Brain (cerebellum), Brain (brain stem + medulla oblongata), Heart (L ventricle), Heart (R ventricle), Esophagus, Lung (R lobe), Lung (L lobe), Liver (R lobe), Liver (L lobe), Liver (quadrate lobe), Kidneys (L), Kidneys (R), Lymph nodes (mandibular), Lymph nodes (sup. Cervical), Lymph nodes (mediastinal), Spleen, Ovary / Testis, Salivary Glands, Stomach, Duodenum, Jejunum, Ileum, Colon, Cecum, Rectum, Pancreas, Tongue, and Buccal Mucosa) were sent to the histopathology examination.

Results

No clinical signs were observed in the animals during the trial.

No difference between study groups (treatment arms versus placebo) was observed in the pigs weight, organs (brain, lungs, heart, liver, spleen, kidneys) weight. The blood tests did not demonstrate variability between study groups (treatment versus placebo).

Based on the results we can conclude that CimetrA® was found safe in animal models in two doses. These results will support the IND submission to the FDA and future clinical studies in Phase IIb and III. Phase IIb study includes efficacy endpoints and dose finding elements, based on the current animal study results. Current study results support the CimetrA® treatment regimen defined in Phase IIa clinical study in COVID-19 patients and will be used in the future clinical studies.

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