

7 December 2020

ASX Code: MXC

## ArtemiC™ Phase II Clinical Trial Results Update

### Key Highlights:

- Full results from completed ArtemiC™ Phase II double-blind, placebo controlled clinical trial are expected in the next 7 days
- ArtemiC™ is intended for cytokine storm and clinical deterioration prevention to support the recovery of COVID-19 infected patients
- ArtemiC™ also has potential applications for a wide range of medical conditions, such as influenza, pneumonia, Acute Respiratory Syndrome and support of oncology patients receiving chemotherapy treatments
- Interim Results reported to date demonstrate ArtemiC™ has met all primary end points for safety and efficacy, and FDA primary endpoint of sustained clinical recovery of COVID-19 patients
- In preparation of completed results, MGC Pharmaceuticals is working on the potential reclassification and registration of ArtemiC™ to an Investigative Medicinal Product
- As previously announced, two acute tox *in vivo* preclinical trials (in two types of rodents – mice and rats) that include a full histopathology profile demonstrated the full safety profile of ArtemiC™ and determined the maximum tolerated dose of the drug.
- Following receipt of positive results, ArtemiC™ will move to production at MGC Pharmaceutical's EU-GMP Certified production facility in Slovenia

**MGC Pharmaceuticals Ltd (ASX: MXC, 'MGC Pharma' or 'the Company')**, a European based biopharma company specialising in the production and development of phytocannabinoid-derived medicines, is pleased to confirm the independent statistical verification of results of the 50 patient Phase II double-blind, placebo controlled clinical trial to evaluate the safety and efficacy of the natural anti-inflammatory formulation ArtemiC™ on patients diagnosed with COVID-19 (the 'Trial') are nearly complete.

Full results from the Trial are expected in approximately 7 days which will follow independent technical review and statistical validation of the data which is managed by an external Clinical Research Organization (CRO) under required regulatory conditions addressing FDA (Food and Drug Administration) requirements and following GCP (Good Clinical Practice) guidelines.

The Company released interim results from the first ten (10) patients recruited (refer ASX release 20 August 2020) to the Trial which demonstrated ArtemiC™ met all its primary end points for the safety and efficacy of the treatment.

The trial results are looking to support widespread applications to effectively treat the symptoms of COVID-19 patients prior to them requiring hospital admission and or potentially shorten their stay as inpatients, and thus relieve the pressure on global healthcare systems caused by COVID-19.

ArtemiC™ related to COVID-19 and other life-threatening conditions demonstrated during a pre-clinical *in-vivo* safety and histology study in rats there was no pathological changes in all the tested animal samples (refer ASX release 14 October 2020).

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In anticipation of the Trial results, the Company is working on the CMC (Chemistry, Manufacturing and Controls) which is part of the registration document of medicine for the reclassification of ArtemiC™ from a pharmaceutical product to an Investigation Medicinal Product (IMP). The reclassification of ArtemiC™ to an IMP will then come within the Botanical Drug bracket.

Upon completion of the Trial and the release of positive results, the production of ArtemiC™ will move to MGC Pharma's GMP Certified production facility in Slovenia. The Company expects to rapidly advanced discussions on a commercial scale for ArtemiC™ supply agreements on publication of data which determine the Trial a success.

Additionally, the Company is exploring the wider uses of ArtemiC™ to encompass other conditions that cause cytokines storm.

**Roby Zomer, Co-founder and Managing Director of MGC Pharma, commented:** "Our Company continues to progress initiatives designed to fast-track pathways to market ahead of the Phase II results for ArtemiC™, in order to be in a position to be responsive to potential market demand."

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## About MGC Pharma

MGC Pharmaceuticals Ltd (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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