5 November 2020

ASX Code: MXC

Completion of ArtemiC™ Phase II clinical trial on COVID-19 infected patients, targeting sustained clinical recovery

Key Highlights:

- ArtemiC™ Phase II clinical trial on fifty (50) patients infected with COVID-19 has been completed
- This double-blind placebo-controlled Phase II Clinical Trial is designed to evaluate the safety and efficacy of the natural anti-inflammatory formulation ArtemiC™ in patients diagnosed with COVID-19, and evaluate their recovery rates
- As announced on 20 August 2020, interim results from the first 10 patients in Israel in the Trial met all primary end points for the safety and efficacy of the treatment ('Interim Results')
- Interim Results met key FDA primary endpoint of sustained clinical recovery, preventing the need of intensive care in high risk patients or invasive mechanical ventilation
- Final results of the 50 patient Phase II clinical trial are expected to be published in the next month following independent technical review and statistical validation of the trial data
- MGC Pharma well positioned to fast-track production of ArtemiC™ to meet future demand post publication of full clinical trial results, with potential for material commercial contract supply opportunities on the back of positive results from the full Trial validating the Interim Results
- The Company is now designing protocols and parameters for next phase of the international multi-centre clinical trial with endpoints and study population to be defined according to FDA guidelines[1], subject to positive Trial results
- Immediate opportunity to pursue commercial supply agreements with second wave outbreaks of COVID-19 pandemic currently across the UK, America's, Europe, Russia/CIS countries, Israel and the Middle East with 3,355,265 new cases of COVID-19 being reported globally in the last 7 days according to the World Health Organisation's weekly situation report[2]

MGC Pharmaceuticals Ltd (ASX: MXC, 'MGC Pharma' or 'the Company'), a European based bio-pharma company specialising in the production and development of phytocannabinoid-derived medicines, is pleased to announce the completion of the 50 patient Phase II double-blind, placebo-controlled clinical trial for anti-inflammatory treatment, ArtemiC™, on patients diagnosed with COVID-19 to evaluate the safety and efficacy ('the Trial').

The key objective of the Trial is to meet the key FDA primary endpoint of sustained clinical recovery, preventing the need of intensive care in high risk patients or invasive mechanical ventilation.

Full results of the Trial are expected to be published in the next month following independent technical review and statistical validation of the Trial data which is managed by an external Clinical Research Organization (CRO) under required regulatory conditions answering FDA (Food and Drug Administration) requirements and following GCP (Good Clinical Practice) guidelines.

Should the full Trial results validate data received from the Interim Results, the Company is well positioned to fast-track production of ArtemiC™ immediately as a food supplement to meet expected demand for potential material contract supply opportunities.

[1] FDA Guidelines on COVID-19
[2] WHO Weekly Report – 1 November 2020

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Following receipt and analysis of the full 50 patient data set that determines the Trial a success on the back of positive results, MGC Pharma will finalise designing protocols, parameters and timing to commence a Phase III clinical trial which will be the next phase of the clinical research, this will include an international multi-centre study with endpoints and the study population to be defined according to guidelines set by the US FDA.

Trial Background

The Trial results are looking to support widespread applications to effectively treat the symptoms of COVID-19 patients prior to them requiring hospital admission or alternatively shorten their stay as inpatients, and thus relieve the pressure on global healthcare systems caused by COVID-19. The effective treatment of symptoms of COVID-19 has been deemed important by the FDA.

The Company released interim results from the first ten (10) patients recruited (refer ASX release 20 August 2020) to the Trial which showed ArtemiC™ met all its primary end points for the safety and efficacy of the treatment. The Company looks forward to releasing results of the remaining forty (40) patients in the coming month.

The Trial is seeking to evaluate the safety and efficacy of ArtemiC™ and its ingredients (consisting of Artemisinin, Curcumin, Boswellia serrata, Vitamin C) on patients infected with COVID-19. Pleasingly, the interim data showed a beneficial effect of ArtemiC™ on the related pain associated with COVID-19 with none of the actively treated participants reporting pain on the 15th day concluding the active monitoring phase, as opposed to those treated with placebo who all continued to experience some level of pain.

Market Potential

With widespread outbreaks of new COVID-19 cases associated with a second wave of the pandemic now moving across several countries in the America's, Europe, Russia/CIS countries and the Middle East, there is an immediate opportunity for the Company to continue to progress its clinical trial work. The Board believe positive results from the Trial have the potential to deliver material commercial supply opportunities for ArtemiC™ immediately as a food supplement.

According to the World Health Organisation's weekly situation report there have been over 3 million new cases in the past 7 days, the highest number of weekly new COVID-19 cases reported globally since the outbreak[2].

Dr Jonathan Grunfeld, Chief Medical Officer of MGC Pharma, commented: *"ArtemiC™ is a formulation comprising several active ingredients, each of which is associated with multiple therapeutically relevant biological effects. The logic embodied in the ArtemiC™ clinical approach may be metaphorically represented in a concept of a "Silver Blanket" in contra-distinction to the "Silver Bullet" solution approach. The idea is to simultaneously obstruct multiple processes driving the disease in attempt to smother its progression rather than precisely disrupt specific processes considered to be crucial to its further development.*

The experience accumulated so far with "Silver Bullet" therapeutics such as specific disruption of isolated cytokine activities or distinct molecular events required for viral penetration into cells of the lungs or replication, and so on, have all failed to provide a satisfactory remedy for COVID-19. The shortcoming of this approach has already gained recognition in attempts to combine more than one "Silver Bullet" in recently designed protocols. ArtemiC™ takes the "Silver Blanket" approach one step further in that it combines ingredients with pleiotropic effects."

Roby Zomer, Co-founder and Managing Director of MGC Pharma, commented: *"We are very pleased to announce the completion of the Phase II clinical trial for ArtemiC™. The second wave of the pandemic is again putting increased pressure on a number of healthcare systems around the world. We look forward to announcing full results of this trial in coming weeks and will continue to progress this important clinical trial work."*

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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 and Brazil 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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