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ASX Code: MXC

ArtemiC™ Phase II Clinical Trial Results on COVID-19 patients confirm 100% of treatment group successfully met primary and secondary endpoints

Key Highlights:

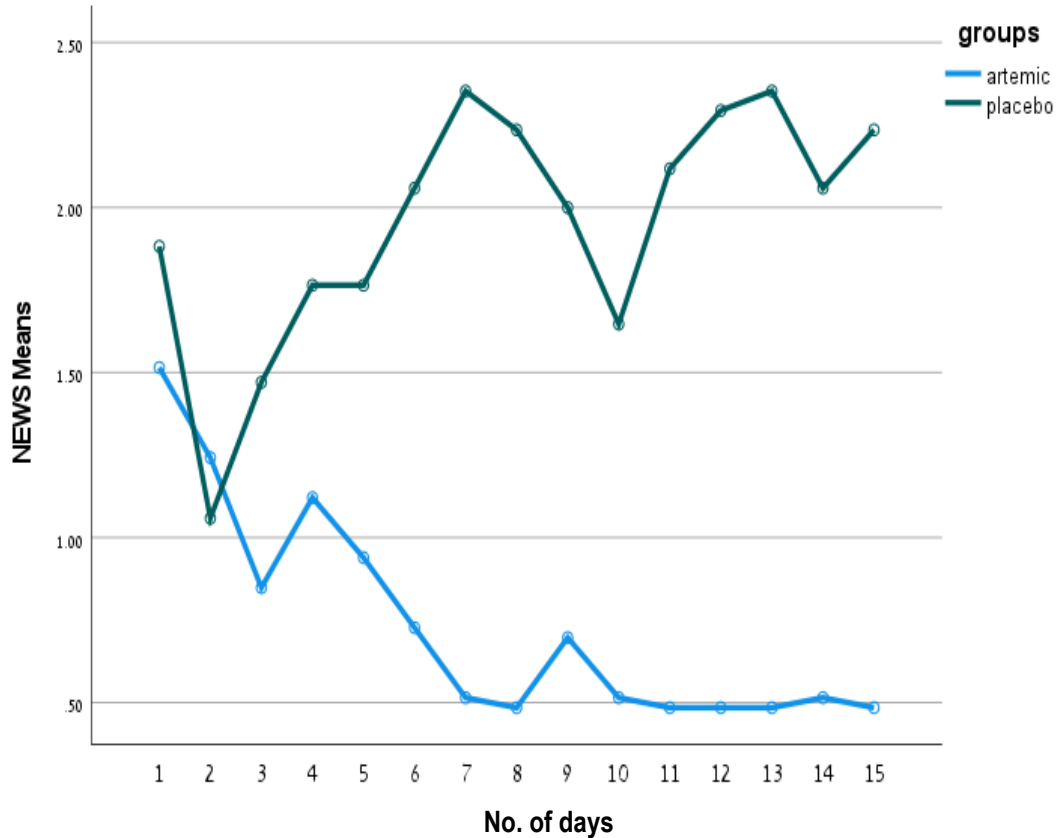
- Full results of MGC Pharma’s phase II double blind clinical trial show ArtemiC™ has successfully met the primary and secondary study endpoints
- ArtemiC™ statistically significantly improved the clinical recovery of 50 COVID-19 infected patients in the treatment group in comparison with placebo.
- 100% of the patients in the treatment group met the Trial’s primary end point and fully recovered within 15 days of follow up
- ArtemiC™ delivered a NEWS score (main parameter of clinical improvement in COVID-19 patients) of less than or equal to 2 in 100% of patients in the treatment group
- The Trial met all the FDA requirements for a COVID-19 study including population diversity
- None of the patients in the treatment group required additional oxygen, mechanical ventilation or admission to intensive care, in comparison with 23.4% of the placebo group requiring further assistance
- ArtemiC™ results deliver a full safety and efficacy profile, demonstrating to improve and expedite the clinical recovery in moderate COVID-19 patients
- Full Trial results are supported by *in vitro* and *in vivo* studies, demonstrating the mechanism of action and safety profile of ArtemiC™
- These results now open potential market opportunities for ArtemiC™ to a wide range of diseases related to cytokine storm such as autoimmune diseases, inflammatory GI diseases, ‘flu and chemotherapy patients
- Next steps for the product development will include immediate evaluation of a Phase III Trial in COVID-19 and ‘flu patients and classification of ArtemiC™ under new name as IMP (Investigational Medicinal Product) which will be produced in MGC EU GMP facilities
- Following successful Phase III Trial results ArtemiC™ can be produced and sold by the Company as a supplement, through its existing production facilities and distribution networks

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 full results of its Phase II double-blind, placebo-controlled clinical trial for anti-inflammatory treatment ArtemiC™, based on Swiss PharmaCan AG MyCell Enhanced™ delivery system technology (‘MyCell™’), on persons diagnosed with COVID-19, has successfully met all the Phase II primary and secondary endpoints and demonstrated to improve the clinical recovery of COVID-19 patients. The (“Trial”).

Key Trial Results

The Company has completed its Trial on ArtemiC™ on 50 infected patients across 3 independent hospital sites in Israel and India, 50 patients were recruited to the trial, 33 in the treatment group and 17 in the placebo group.

The full results have demonstrated to improve the health status of COVID-19 patients delivering a NEWS score of less than or equal to 2. None of the patients in the treatment group required additional oxygen, mechanical ventilation or admission to intensive care where all of these events were reported in the placebo group. The average NEWS score of patients in the placebo group was 2.25 statistically significantly higher ($p < 0.04$) than in the treatment group – 0.5.



The improvement of NEWS in treatment group vs placebo group is demonstrated in Figure 1.

Figure 1. Daily improvement of NEWS parameter in both study groups, $p < 0.04$

Additionally, ArtemiC™ demonstrates the following distinct advantages.

- A full safety and efficacy profile with no drug-adverse events
- The ability to prevent deterioration of COVID-19 patients and achieve faster clinical improvement
- The ability to assist in reducing the pressure on the medical system and support coping with hospitalised patients
- The ability to improve symptoms and pain associated with COVID-19
- The versatility to be used in community as well as in hospitals
- As the mechanism of action of ArtemiC™ is focused on the anti-inflammatory effect and prevention of cytokine storm, a wide spectrum of potential indications will be considered for future development

NEWS score determines the degree of illness of a patient and prompts critical care intervention. This was defined as a main tool for the estimation of COVID-19 patients clinical health status and improvement.

The comparison between the study and placebo groups before and after treatment is presented in **Table 1**.

Study visit	Study group	NEWS Score	P
Before treatment	ArtemiC™	1.5152	0.54
	Placebo	1.8824	
Day 15	ArtemiC™	.5152	0.04
	Placebo	2.2353	

In line with the interim results released on the 20th August 2020, the Trial met all the FDA requirements for a COVID-19 study including population diversity (age, medical history, and genetic diversity) and demonstrated a full safety profile with no drug related adverse events. This resulted due to ArtemiC™ and the Trial being focused on the immunomodulation specific for the prevention of cytokines storm, as opposed to other immunomodulators.

These results also follow safety and toxicity testing completed on mice (refer ASX release 27 July 2020) and in line with FDA requirements for product registration requiring two types of rodents in pre-clinical trials, MGC Pharma completed an in vivo safety and toxicity pre-clinical study, including histology testing, on 24 rats. This included 4 groups with three 3 study drug dosages being 48ug, 96ug and 196ug per kg rat and a control group. The rats were observed and tested for clinical changes over seven days. This study included pathological examination of the organs: liver, heart, brain, spleen, spinal cord, sciatic nerve, kidney (L+R), lungs and tongue.

The results concluded there were no pathological changes in all tested animal samples.

Next steps

Following the successful Phase II results, further development for ArtemiC™ will include immediate evaluation of a Phase III clinical study on COVID-19 and flu patients, and production in MGC EU GMP facilities as IMP under a new brand name. In addition, different indications related to inflammation and cytokine storm, will be considered as future development goals and include a wide range of diseases related to cytokine storm such as autoimmune diseases, inflammatory GI diseases, flu and chemotherapy patients.

The Company is in a strong position to respond to a significant potential increase in the demand for ArtemiC™ in the immediate future as a supplement, and in the future as part of a Phase III study where the Company would look to develop ArtemiC™ as a pharmaceutical product and future development as an Investigational Medicinal Product (IMP).

Regulatory approvals to commence the Phase III Clinical Trial will be progressed with Anvisa (Brazilian medical Authority), EU Novel Food authority and submissions are expected to be made in first quarter of 2021. The Company plans to develop and commence a Phase III Clinical Trial in the first half of 2021. The Phase III Clinical trial is anticipated to be an international multicentre study with up to 250 patients and expand its research to encompass a wide range of inflammatory indications for the use of ArtemiC™ as a treatment. These indications are related to cytokines storm as autoimmune diseases (rheumatoid arthritis, lupus), flu, chemotherapy patients and IBD could benefit from the mechanism of action ArtemiC™, demonstrated in preclinical and clinical trials.

Upon completion of a successful Phase III Clinical Trial the Company will seek registration of ArtemiC™ and commence production and sale as a supplement, through its existing production facilities and distribution networks.

Successful results of Phase III will lead for a pre-IND meeting with FDA in order to initiate the registration process for ArtemiC™ as an IMP.

The ArtemiC™ clinical study on COVID-19 patients is managed under GCP requirements and local Helsinki Committee approvals in 3 hospitals in Israel and 1 in India. The independent management of the study was performed by Dr Nadya Lisovoder, CEO of Galilee Clinical Bio Research, an external Clinical Research Organization (CRO), under all required regulatory conditions answering FDA requirements. Galilee-CBR is an independent Clinical Research Organisation located in Israel provides a full spectrum of clinical development phases I to IV in pharma and medical devices. Galilee-CBR is working with an Israeli Government for the bio medical research promotion in the hospital in Northern Israel. Certified Electronic Data Capture system (provided by Flask Data company, specializes in EDC systems for FDA and EMA clinical trials) was used for the data collection and 100% of the study data was monitored in order to ensure the data quality. Statistical analysis of the results was performed by an external and independent biostatistician, Dr. Nira Morag, a senior lecture in Tel Aviv University, Department of Biostatistics. Nira has more than 30 years of experience in biostatistics in pharma industry.

Roby Zomer, Co-founder and Managing Director of MGC Pharma, commented: “The results we have seen from ArtemiC™ to date provide a transformational opportunity for the Company. The safety and efficacy demonstrated on COVID-19 patients has now opened the opportunity for a whole range of other indications related to cytokine storm. The Company will now look to progress the immediate opportunities for ArtemiC™ while continuing to pursue further clinical developments.”

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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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ANNEXURE A – DETAIL ON INITIAL ANALYSIS FROM PHASE II ARTEMIC™ TRIAL

Name and any unique identifier of the trial:	A Phase II, double blind placebo controlled clinical trial designed to evaluate the effect of ArtemiC in patients diagnosed with COVID-19 (ID: MOH_2020-04-16_008859; ClinicalTrials.gov Identifier NCT04382040)
Blinding status:	Double Blinded
Treatment method, route, frequency, dose levels:	<p>Agent name and composition: ArtemiC, medical spray composed of a combination of 6 mg/ml of Artemisinin and 20 mg/ml of Curcumin.</p> <p>Dose: Maximum dose during a day by medicated spray, divided over 2 times day.</p> <p>Study Procedures: The study will last 2 weeks and additional time required for follow up till hospital discharge in order to check side effects and study drug efficacy.</p> <p>Methodology: Safety will be assessed through collection and analysis of adverse events, blood and urine laboratory assessments and vital signs. After Screening visit, the study drug will be administrated during 2 days twice a day. All patients will be monitored till the hospital discharge.</p>
Number of trial subjects:	50
Dropout rate:	1 patient in Placebo Group dropped out on Day 13 (out of 15) due to SAE, ICU admission, ventilation and transfer to other hospital. The patient was included in the statistical analysis.
Subject demographics:	<p>33 patients were randomized to the Treatment Group. Demographical characteristics –</p> <ul style="list-style-type: none"> - 17 males and 15 females - Mean age – 52±14 - 22 Caucasians, 1 Black, 9 Asians - 26 non smokers, 6 smokers. - Mean weight - 74.2 ±14.5 - Mean height - 168± 8.5 - Mean BMI - 25.5± 3.1 <p>Patients medical history included diabetes, chronic respiratory system diseases, obesity, renal failure, obesity.</p>
Control Group:	<p>17 patients were randomized to the Treatment Group. Demographical characteristics –</p> <ul style="list-style-type: none"> - 8 males and 9 females - Mean age – 53± 14 - 16 Caucasians, 1 Asian - 11 non smokers, 6 smokers. - Average weight - 72.3± 13.6 - Average height - 168 ±9.1 - Average BMI – 26.2 ±3.5
Primary endpoint(s):	<ul style="list-style-type: none"> • Time to clinical improvement, defined as a national Early Warning Score 2 (NEWS2) of <= 2 Maintained for 24 Hours in comparison to routine treatment <p>All patients in the study group met the primary endpoint and had NEWS score less than 2 (0.5 with St. Dev. 0.51) at discharge, while the average NEWS score in the placebo group was 2.23 (St. Dev. 3.19). this difference was a statistically significant (p<0.04).</p> <ul style="list-style-type: none"> • Percentage of participants with definite or probable drug related adverse events <p>The safety was assessed by AEs and laboratory tests. In the Treatment group no drug related SAEs AEs were reported. In the Placebo group 1 AE was reported (Acute respiratory distress syndrome), that was defined as unlikely related to study drug.</p>

	Serious Adverse Events are presented in the table below -	
	Artemic	Placebo
Number of patients	9 patients: (max severity) Mild 4 Moderate 4 Severe 1	7 patients: (max severity) Mild 5 Moderate - 0 Severe 2
Number of events	13 events: Mild 6 Moderate 5 severe 2	16 events: Mild 13 Moderate 1 Severe 2
Secondary endpoints:	<ul style="list-style-type: none"> Time until negative PCR <p>Placebo group: 1 missing data (due to drop out of the ventilated patient), 8 Negatives on day 15. 8 positive.</p> <p>Study group: 3 missing, 17 Negative, 13 Positive on day 15.</p> <ul style="list-style-type: none"> Proportion of participants with normalization of fever and oxygen saturation through day 14 since onset of symptoms <p>0 patients in Treatment Group 4 patients in Placebo Group</p> <ul style="list-style-type: none"> COVID-19 related survival <p>1 patient is in life threatening condition (Placebo group) related to COVID-19. 1 patient (Placebo group) – death related to COVID-19 is reported 2 days after study completion.</p> <ul style="list-style-type: none"> Incidence and duration of mechanical ventilation <p>Two patients (Placebo group) was on mechanical ventilation.</p> <ul style="list-style-type: none"> Incidence of Intensive Care Unit (ICU) stay <p>Two Patients randomized to Placebo group was transferred to ICU.</p> <ul style="list-style-type: none"> Duration of ICU stay <p>One patient was hospitalized in the ICU for 1.5 month (Placebo group) One patient for 5 days and death related to COVID was reported.</p> <ul style="list-style-type: none"> Duration of time on supplemental oxygen <p>The patient from Placebo group was on the supplemental oxygen for 1.5 months Second patient from Placebo group was on the supplemental oxygen for 5 days</p>	
Safety and tolerability:	No AEs related to the study drug were reported during a study. One unlikely related AE was reported in the patient from the Placebo group.	