20 December 2021

ASX Code: MXC

LSE Code: MXC

ASX RELEASE

Clinical Study commenced on the influence of ArtemiC Support® on patients with Long COVID Syndrome

Key Highlights:

- Clinical Study underway with partners Swiss PharmaCan AG and Glow LifeTech Ltd to determine the influence of MGC Pharma's proprietary supplement ArtemiC Support® in patients with Long COVID syndrome.
- The Clinical Study received Ethics Committee approval from Spanish research foundation, IDIAP Jordi Gol, on 9 December 2021.
- The Clinical Study will enrol 150 patients suffering from post-acute COVID syndrome (Long COVID syndrome), with 50 patients already enrolled, and is expected to be completed in February 2022.
- Patients will take ArtemiC Support® for 6 weeks under supervision of their doctor, with their progress measured against a Post-COVID Functional Scale (PCFS), and a 10-point Likert scale, one, two, three and six weeks after treatment commences.
- This is a pilot study to initially obtain partial results on the effectiveness and safety of ArtemiC Support® in improving the functional status and symptomatology in patients suffering from Long COVID Syndrome.
- A further randomised, double-blind, placebo-controlled study, to get full information on efficacy and safety of the food supplement in patients suffering from Long-COVID is expected to follow, dependent on the results of the initial pilot study.

MGC Pharmaceuticals Ltd ('MGC Pharma' or **'the Company'),** a European based bio-pharma company specialising in the production and development of phytomedicines is pleased to announce that it is co-sponsoring a Clinical Study into the influence of MGC Pharma's proprietary supplement, ArtemiC Support®, in patients with Long COVID Syndrome.

Long COVID or post-acute COVID syndrome, refers to the ongoing health problems that people can experience four or more weeks after first being infected with SARS-COV-2, the virus responsible for COVID-19.[1] This condition is believed to affect 10–35% of all COVID-19 patients.[2]

The Study is being sponsored by MGC Pharma's distribution partner, Swiss PharmaCan AG ('SPC') and is co-sponsored by MGC Pharma and Glow LifeTech Ltd. The study received Ethics Committee approval from Spanish Foundation, IDIAP Gordi Gol, on the 9th of December 2021 and is now underway, with 50 of the targeted 150 patients enrolled.

In total, 150 patients suffering from Long COVID Syndrome will be enrolled into the Spanish study. Patients will administer ArtemiC Support® for 6 weeks under supervision of their doctor, with their progress being measured using a Post-COVID Functional Scale (PCFS)[3] and a 10-point Likert scale 1, 2, 3 and 6 weeks after treatment initiation. The symptoms measured include:

1. Dyspnea - shortness of breath
2. Asthenia - abnormal physical weakness or lack of energy
3. Anosmia - loss of senses of smell
4. Ageusia - loss of sense of taste
5. Cough
6. Headache
7. Mental confusion

The study has commenced and is expected to conclude in February 2022, subject to enrolment targets being achieved, and results published in Q2 2022. Dependent on the findings, it is anticipated that a further randomised, double-blind, placebo-controlled study, to get full information on efficacy and safety of **ArtemiC Support®** in patients suffering from Long COVID Syndrome will follow.

1. https://www.cdc.gov/coronavirus/2019-ncov/long-term-effects/index.html
2. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8093949/
3. https://erj.ersjournals.com/content/early/2020/05/07/13993003.01494-2020

info@mgcpharma.com.au | mgcpharma.com.au
MGC Pharmaceuticals Ltd | 1202 Hay Street, West Perth, WA 6005
PO Box 1976, West Perth WA 6872
T: +61 8 6382 3390

ArtemiC Support® is the second product in the Company's **ArtemiC™** product range to progress to the Clinical Trial phase to determine their safety and efficacy against SARS-COV-2 related diseases. In 2020 MGC Pharma undertook a Phase II Clinical Trial for **ArtemiC™** to determine its safety and efficacy in patients diagnosed with moderate COVID-19, and to evaluate their recovery rates. (*refer ASX Announcement dated 15 December 2020)*

About ArtemiC™

ArtemiC™ is a clinically tested food supplement (nutraceutical, dietary supplement, natural health product) containing four natural based ingredients consisting of Artemisinin, Curcumin, Boswellia serrata, and Vitamin C.

In a Phase II double-blind, placebo-controlled Clinical Trial on 50 patients with moderate COVID-19, **ArtemiC™** demonstrated the following 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 reduce symptoms and pain associated with COVID-19
- The versatility to be used in community as well as in hospitals

Roby Zomer, Co-founder and Managing Director of MGC Pharma, commented: "*This study is a crucial first step in determining whether **ArtemiC Support®** helps Long COVID sufferers by treating what is often are very debilitating conditions.*

*Working with our partners Swiss PharmaCan and Glow LifeTech, we are hopeful that this study will demonstrate that **ArtemiC Support®** is as successful at helping patients with Long COVID, as the Phase II study undertaken in 2020 indicated that ArtemiC™ was in treating patients with moderate COVID-19. We look forward to publishing the results as soon as practicable, and hopefully extending the use of **ArtemiC Support®** to a new group of patients*."

Dr. Dieter Russman, Swiss PharmaCan's Responsible Person for this study commented: "*In October 2021 Swiss PharmaCan gave the green light for a Clinical Study on the Influence **of ArtemiC Support®** in patients with Long COVID. I'm expecting highly valuable results on the safety and efficacy of **ArtemiC Support®**, based on its breakthrough MyCell technology, and the potential benefit for millions of people suffering from Long COVID, who to date, have had limited therapeutic options available to them*."

--Ends--

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

MGC Pharmaceuticals Ltd
Roby Zomer
CEO & Managing Director
+61 8 6382 3390
info@mgcpharma.com.au

MGC Pharmaceuticals Ltd
David Lim
Company Secretary
+61 8 6382 3390
info@mgcpharma.com.au

UK Broker – Turner Pope
Andy Thacker
+44 203 657 0050
info@turnerpope.com

UK PR Advisors – Tavistock
Charles Vivian / Tim Pearson
+44 207 920 3150
mgcpharma@tavistock.co.uk

About MGC Pharma

MGC Pharmaceuticals Ltd (LSE: MXC, ASX: MXC) is a European based bio-pharma company developing and supplying affordable standardised phytomedicines 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.

Follow us through our social media channels

ANNEXURE A
ArtemiC Support® Study Protocol

Name and any unique identifier of the trial:	Clinical Study on the Influence of ArtemiC Support® in patients with Long COVID
Primary endpoint(s):	Functional status, according to Post-COVID Functional Scale (PCFS) one, two, three and six weeks after treatment initiation.
Secondary endpoints:	Symptomatology according to the 10-point Likert scale one, two, three and 6 weeks after treatment initiation. Symptoms measured will be: 1. Dyspnea 2. Cough 3. Asthenia 4. Anosmia 5. Ageusia 6. Headache 7. Mental confusion
Blinding status:	N/A
Product status:	Each participant will be provided with two 30 ml jars of ArtemiC Support. The Sponsor will provide the Food Supplement free of charge for patients. Each treatment will be identified with a unique code. The medication sent to the centres, dispensation, return and destruction will be collected in the correspondent registers. Responsibility for production and supply, is with Swiss PharmaCan AG with a Responsible Person in place.
Treatment method, route, frequency, dose levels:	<u>Study Product:</u> Arm 1: ArtemiC Support: The active compounds in ArtemiC Support are Boswellia serrata, Curcuma longa and Vitamin C and uses the drug delivery system to increase bioavailability. <u>Study Procedures:</u> The collection of data will be done by in person interviews (mandatory at first assessment) and by in person interviews or phone calls after one, two, three or six weeks. Day one (1) is the day of first intake. On the day of inclusion and first assessment, the investigator will carefully explain the aim and the design of the study and handover a relevant information sheet. Data will be collected by healthcare professionals, either nurses or medics. Only medical doctors to sign up the relevant documents.

	Any side effects, possibly related to the intake of ArtemiC Support, will be carefully documented and reported as appropriate, in line with GCP vigilance rules. The statistical analysis will be descriptive. Description will be made for the change in scale, based on the PCFS questionnaire, comparing average scales on day of inclusion with those after one, two, three and six weeks, as well as the subgroups Scale 1, Scale 2, Scale 3 and Scale 4 on day of inclusion with those after one, two, three and six weeks. Methodology: Low intervention, single arm open study of 150 patients who suffer from post-acute COVID Syndrome. It is the investigator's responsibility to detect and document any event that meets the criteria and definitions of an Adverse Event (AE). It is also the responsibility of the investigator to report all Adverse Events that are considered serious. The AEs will be collected through spontaneous communication of the patient, and at every interview through an open questioning by the investigator. Information about the AE, including start and end date, description of the event, security, evolution, outcome, relationship of the AE with the food supplement and measures taken will be recorded in the Case Report Form. Participants AE/Adverse Reactions (AR) will be followed up during the remaining visits until the end of the study. The causal relationship between the investigational product and the appearance of an Adverse Event/ Serious Adverse Event (SAR) will be established, based on clinical judgment. For this, other causes will be considered and studied, such as the natural history of the underlying diseases, concomitant treatment, other risk factors and the temporal relationship of the event with the investigational product.
Number of trial subjects:	Total of 150 patients in Spain who suffer from post-acute COVID Syndrome (Long COVID Syndrome).
Description of Control Group:	N/A
Subject selection criteria:	Inclusion Criteria: • Age 18 – 80 years • Suffering from post-acute COVID Syndrome • Persisting post-acute COVID syndrome symptomatology of more than one month, with Post Covid Functional Score (PCFS) between one and four. • The patient must be able to complete the follow-up assessments. • The patient agrees to participate in the study and to take the assigned medication during the 6 weeks. • The patient signs the informed consent Exclusion Criteria: • Known hypersensitivity to ArtemiC Support • Active malignancy • Current or recent chemotherapy treatment (<6 months) • Medical history of Human Immunodeficiency Virus (HIV) infection, or any serious immunocompromised state • Use of montelukast or zafirlukast ≤ 30 days previous to the inclusion • Having participated in another clinical trial in the previous month

Trial locations:	Spain
Name of the principal investigator:	Dr. Carlos Brotons
Partners:	Swiss PharmaCan AG, Glow LifeTech Ltd, MGC Pharmaceuticals Ltd, Universal Doctor and EAP Sardenya
Expected duration:	The Trial commenced on 10 December 2021 and is expected to conclude in February 2022
Additional information:	N/A
Trial standard:	The clinical study follows the principles of the Declaration of Helsinki, the ICH harmonized tripartite guideline for Good Clinical Practice (GCP) and the current legal norm in Spain (Real Decreto 1090/2015, 4 December)