

14 July 2022
ASX Code: MXC
LSE Code: MXC

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

Key Highlights:

- Clinical Study demonstrates the ability of MGC Pharma's **ArtemiC Support®** to reduce severe symptoms of Post-Acute COVID Syndrome (Long COVID).
- Study results demonstrate the statistically significant efficacy of **ArtemiC Support®** in reducing the severity of a range of Long COVID symptoms, including Dyspnea, Cough, Asthenia, Headache and Mental Confusion.
- 150 Patients were administered **ArtemiC Support®** during a 6-week period under the 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 6 weeks after treatment initiation.
- It is estimated that over 50% of patients who recover from COVID-19 have persistent symptoms of Long COVID¹.

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 the successful results of a clinical study into the influence of its propriety product, **ArtemiC Support®**, on patients with Post-Acute COVID Syndrome, also known as Long COVID.

Long COVID refers to the ongoing health problems that people can experience four or more weeks after being infected with SARS-COV-2, the virus responsible for COVID-19. Long COVID is believed to affect more than 50% of all COVID-19 patients¹.

The clinical study, being sponsored by Swiss PharmaCan AG ('SPC') and is co-sponsored by MGC Pharma and Glow LifeTech Ltd, undertaken to obtain partial results on the effectiveness and safety of MGC Pharma's, **ArtemiC Support®**, has demonstrated the ability of the supplement to improve the symptoms of Long COVID.

The Study, undertaken in conjunction with primary care clinicals in Barcelona, CAP Can Bou and Sardenya EAP, was an open label study, commencing with six-weeks of treatment with **ArtemiC Support®**. The Study's objectives were to assess the safety and efficacy of **ArtemiC Support®** in Long COVID patients by measuring the symptoms' severity using a Post-COVID Functional Scale (PCFS).

The study enrolled 150 patients suffering from Long COVID who administered **ArtemiC Support®**, an Oral Spray, for 6 weeks under supervision of their doctor, with their progress being measured using a Post-COVID Functional Scale (PCFS) 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

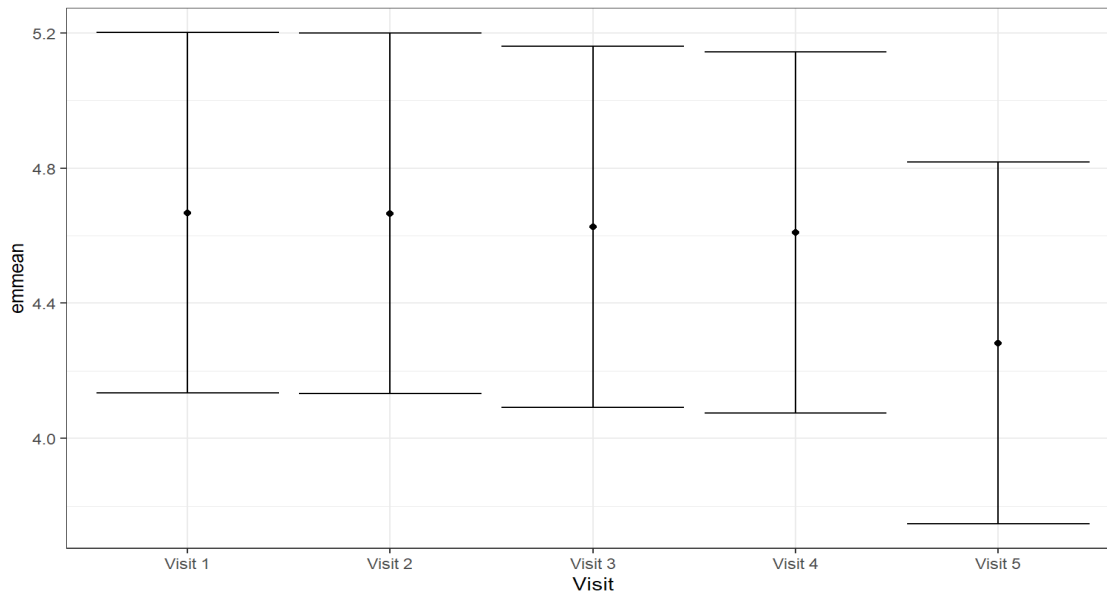
1. <https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1003773>
2. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8093949/>

The results of the study demonstrated **Artemic Support**®'s statistically significant efficacy in reducing the severity of a number of Long COVID symptoms, including Dyspnea, Cough, Asthenia, Headache and Mental Confusion.

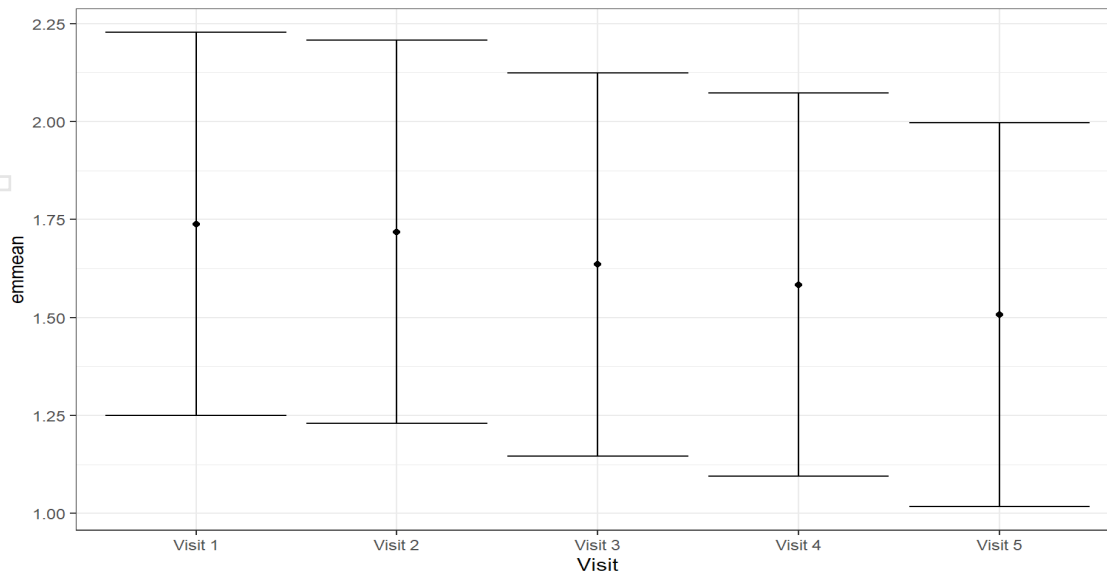
Artemic Support® is the second product in the Company's **Artemic**™ product range to progress to the Clinical Trial phase to determine safety and efficacy against SARS2-COV-2 related diseases. In 2020 the Company completed a Phase II Clinical Trial which demonstrated **Artemic**™'s safety and efficacy in treating patients diagnosed with moderate COVID-19. (refer ASX Announcement dated 15 December 2020)

The graphs below show the Emmeans (Estimated Marginal Mean) observed results from data collected during the **Artemic Support**® Long COVID study:

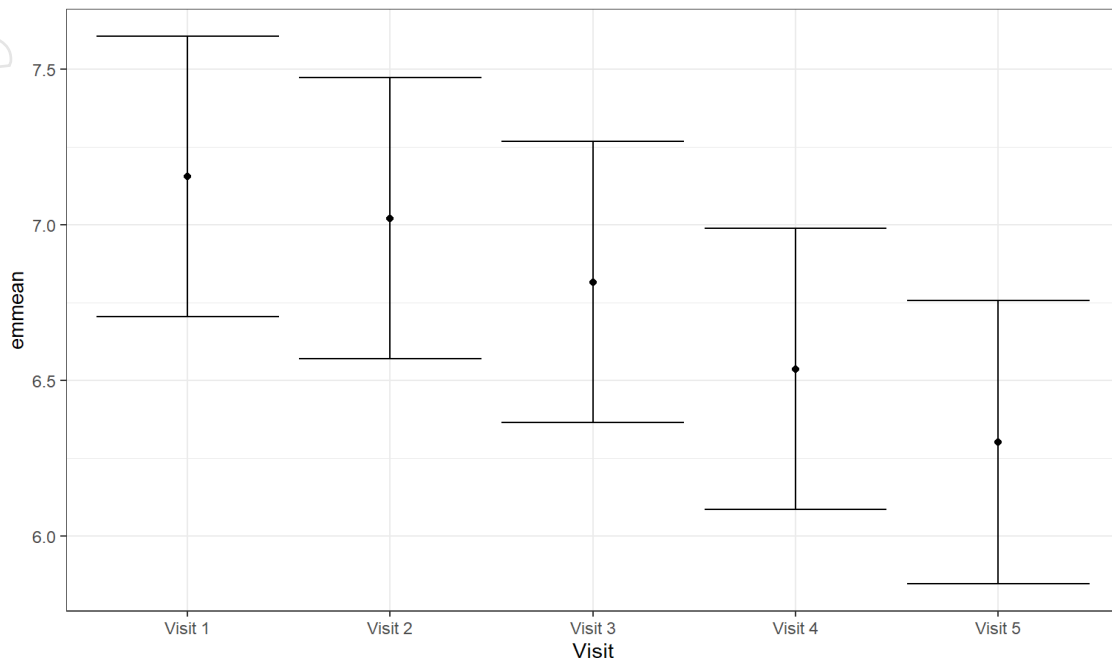
- **Dyspnea:** a significant difference was seen in reported symptom severity (intensity) (visit 5), with a higher emmean indicating higher severity and a lower emmean indicating a lower severity.



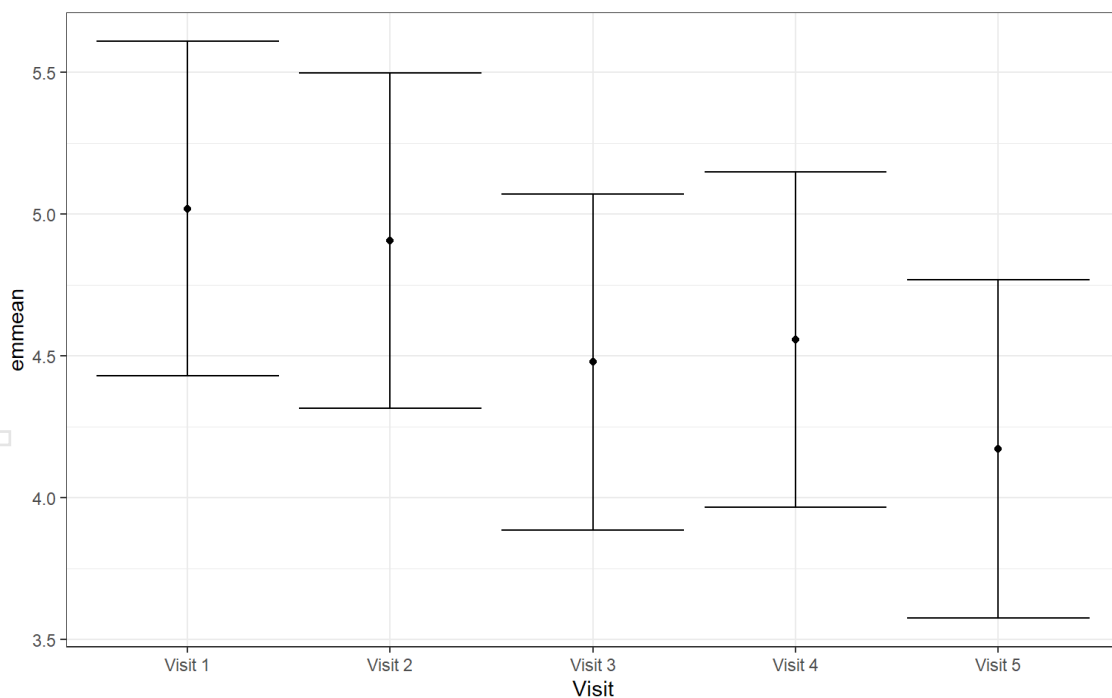
- **Cough:** a significant difference was seen in reported symptom severity (intensity) (visits 4 & 5), with a higher emmeans indicating higher severity and a lower emmeans indicating a lower severity.



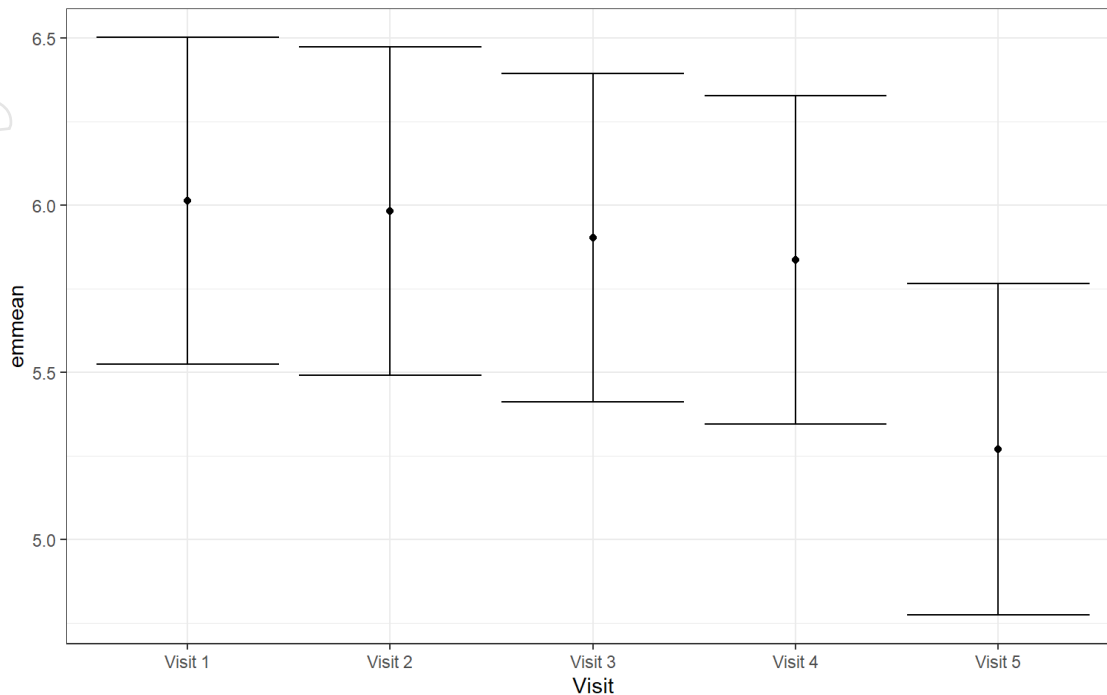
- **Asthenia:** a significant difference was seen in reported symptom severity (intensity) (visit 3, 4 and 5), with a higher emmeans indicating higher severity and a lower emmeans indicating a lower severity.



- **Headache:** a significant difference was seen in reported symptom severity (intensity) (visit 3, 4 and 5), with a higher emmeans indicating higher severity and a lower emmeans indicating a lower severity.



- **Mental confusion:** a significant difference was seen in reported symptom intensity (visit 5), with a higher emmeans indicating higher severity and a lower emmeans indicating a lower severity.



About ArtemiC™

ArtemiC™ is a clinically tested food supplement (nutraceutical, dietary supplement, natural health product) containing natural based ingredients. The nutraceutical, developed by MGC Pharma, incorporates Swiss PharmaCan AG's award winning MyCell™ technology, which increases the bioavailability of **ArtemiC™**'s active ingredients at cell level.

In a Phase II double-blind, placebo-controlled Clinical Trial on 50 patients with 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 setting as well as in hospitals

Roby Zomer, Co-founder and Managing Director of MGC Pharma, commented: "The results of this trial represent a real breakthrough for the Company, and are another step forward in demonstrating the ArtemiC range of product's efficacy in treating patients suffering from both COVID-19 and Long COVID.

Given previous trials, we were optimistic that ArtemiC would prove effective in the current trials, however it is this extremely gratifying to see this born out in a clinical trial undertaken by a Third Party, and we are all very excited about the results and what this means for making our products available to patients who have been suffering with COVID-19 and related diseases for far too long"

--Ends--

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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.

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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: <ol style="list-style-type: none"> 1. Dyspnea 2. Cough 3. Asthenia 4. Anosmia 5. Ageusia 6. Headache 7. Mental confusion
Blinding status:	N/A
Product status:	<p>Each participant will be provided with two 30 ml jars of ArtemiC Support.</p> <p>The Sponsor will provide the Food Supplement free of charge for patients.</p> <p>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.</p> <p>Responsibility for production and supply, is with Swiss PharmaCan AG with a Responsible Person in place.</p>
Treatment method, route, frequency, dose levels:	<p><u>Study Product:</u></p> <p>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.</p> <p><u>Study Procedures:</u></p> <p>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.</p> <p>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.</p> <p>Data will be collected by healthcare professionals, either nurses or medics. Only medical doctors to sign up the relevant documents.</p> <p>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.</p> <p>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.</p> <p><u>Methodology:</u></p> <p>Low intervention, single arm open study of 150 patients who suffer from post-acute COVID Syndrome.</p>

	<p>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.</p> <p>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.</p> <p>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.</p>
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:	<p>Inclusion Criteria:</p> <ul style="list-style-type: none"> • 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 <p>Exclusion Criteria:</p> <ul style="list-style-type: none"> • 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)