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ArtemiC™ update – Approval for sale in the European Union and Clinical Trial results on Indian COVID-19 patients

ASX RELEASE

Key Highlights:

- **ArtemiC™,** MGC's proprietary nutraceutical food supplement designed to support the immune system, has received regulatory approval for sale in Germany and has been issued a Certificate of Free Sale, opening the door to the European Union and international markets.
- **ArtemiC™** utilises Swiss Pharmacan AG's patented MyCell™ technology which increases the bioavailability of the natural ingredients used in the **ArtemiC™** formulation.
- **ArtemiC™** successfully underwent a Phase II Clinical Trial in 2020, which demonstrated efficacy in improving and expediting the clinical recovery of patients with mild COVID-19, as detailed in previous Company announcements
- Separately, as part of the registration process for **CimetrA™** in India, an observational open label controlled Clinical Trial of its sister product **ArtemiC™**, showed that the formulation demonstrated its efficacy in the treatment of patients with **severe** COVID-19 for the first time
- The trial was conducted as part of the process to obtain emergency use authorisation for **CimetrA™** in India (see 3 September 2021 announcement)
- The observational trial included 20 hospitalised patients including ten patients who were in need of oxygen supply, and ten who were on mechanical ventilation.

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 provide a material update on its proprietary nutraceutical food supplement, **ArtemiC™**.

Free Trade Certificate issued in Germany for ArtemiC™, opening EU markets

MGC Pharma has been advised by its global distribution partner, Swiss PharmaCan AG (**SPC**), that it has been issued a Free Trade Certificate in Germany, following the successful completion of a Phase II, multi-centre Clinical Trial on the formulation which demonstrated significantly enhanced recovery of hospitalised patients with COVID-19 compared with placebo controls.

The issuing of a Free Trade Certificate in Germany, noted for its stringency of German food supplement approvals, is likely to significantly accelerate entry into other markets, both within the EU and elsewhere.

ArtemiC™ includes four natural based ingredients consisting of Curcumin, Boswellia serrata, Artemisinin and Vitamin C and incorporates Swiss PharmaCan's MyCell Enhanced™ delivery system technology.

Roby Zomer, Co-founder and Managing Director of MGC Pharma, commented: "The issue of a Free Trade Certificate for **ArtemiC™** Rescue and the **ArtemiC™** Product line in Germany, is a

significant step forward for MGC Pharma as it opens the EU to the marketing and sale of one of the Company's leading products. This is a major commercial milestone for both MGC Pharma and phytomedicines in general, as this approval serves to validate our clinical agenda, and research and development program."

Under the terms of the Supply and Distribution Agreement with SPC (refer announcement 18 February 2021), SPC is responsible for obtaining all relevant permits, approvals, and licences in chosen markets; the Agreement also includes a minimum wholesale order quantity of 40,000 units per quarter.

Clinical Trial demonstrates efficacy against severe COVID-19 in India

As part of the Emergency Use Registration process for **CimetrA™** as a medicine in India, an observational open label controlled Clinical Trial was conducted using a Nasal Formulation (in order to meet the physiological limitation of patients with severe cases of COVID-19) of **CimetrA™,** which was produced in a food grade GMP facility, and released as **ArtemiC™** to the study. The Clinical Study results demonstrated for the first time the formulations efficacy in the treatment of patients with severe COVID-19.

The Clinical Trial demonstrated a significant reduction in one of the main inflammatory markers related to COVID-19, C-reactive protein (**CRP**), an acute inflammatory protein that increases up to 1,000-fold at sites of infection or inflammation. Within COVID-19 patients, CRP is used as one of the main prognostic factors for the clinical deterioration in hospitalised patients.

The Observational Trial, which took place at the Mahatma Gandhi Mission's Medical College and Hospital, included 20 hospitalised patients, including ten patients who were in need of an oxygen supply, and ten who were on mechanical ventilation. For this trial **CimetrA™** was formulated as nasal spray in order to meet the physiological limitation of the severe COVID-19 patients and was produced in Food Grade GMP facility and released as **ArtemiC™** to the study.

This is a significant finding and expands the potential use of **CimetrA™** and **ArtemiC™** to treat patients with severe COVID-19, and further supports previous preclinical and clinical findings for patients with moderate COVID-19, both of which assist placing **CimetrA™** as an anti-inflammatory agent for various inflammatory indication.

Earlier this month, MGC Pharma began the registration process to obtain Emergency Use Authorisation for **CimetrA™** in India (see 3 September 2021 announcement) with partners Medopharm Private Ltd (Medopharm). This Clinical Trial is part of the process to gain authorisation and is expected to be concluded later this year.

Roby Zomer commented: "These latest observational trial results have expanded the possibilities for the use of **ArtemiC™** and **CimetrA™** and their treatment of patients with severe COVID-19. MGC Pharma has always placed the treatment of patients at the heart of everything we do, and these results are very promising signs for those who have been most severely impacted by the disease."

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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 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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About Swiss PharmaCan AG

Micelle Technology AG, parent company of Swiss PharmaCan AG is a dynamic organization dedicated to R&D using natural active ingredients (i.e. vitamins and minerals) to improve human health. As one of the leading innovators of plant-based micelle concentrates, Micelle Technology AG offers a unique technology, which enables the company to harness the full potential of herbal active ingredients.

Website: www.swisspharmacan.ch

Annexure

A Phase II, open label controlled clinical study designed to evaluate the effect of ArtemiC in patients diagnosed with COVID-19

Protocol Title	A Phase II, open label controlled clinical study designed to evaluate the effect of ArtemiC in patients diagnosed with COVID-19
Agent Name and composition	ArtemiC is a medical nasal spray combined of Curcumin (20 mg/ml), Boswellia (15 mg/ml) and vitamin C (60 mg/ml) in spray administration. Patients received up to 40 mg Curcumin, 30 mg Boswellia and 120 mg vitamin C as a maximum dose per 24 hours, given as add-on therapy, 2 times a day, on Days 1 and 2.
Overall rationale	A preparation of ArtemiC, comprising Curcumin, Boswellia, and Vitamin C in a nanoparticular formulation, is proposed as a treatment for the disease associated with the novel corona virus SARS-CoV-2. This initiative is presented under the urgent circumstances of the fulminant pandemic caused by this lethal disease, which is known as COVID-19 and has spread across the globe causing death and disrupting the normal function of modern society. The grounds for the proposal are rooted in existing knowledge on the components and pharmacological features of this formulation and their relevance to the current understanding of the disease process being addressed. The breakout of a lethal pneumonia in the city of Wuhan, China, towards the end of 2019, has led to the characterization of the new coronavirus related disease COVID-19. Its prominent features include a high rate of person-to-person transmission, a substantial risk of developing a lethal respiratory syndrome and potential failure of additional organs. Risk factors for a life-threatening clinical course have been identified, including advanced age and assorted comorbidities, such as cardiovascular disease, diabetes mellitus, hypertension, cancer. However, individuals devoid of any of the recognised risk factors are not immune to the severe manifestation of the disease and once infected carry a certain risk of mortality which has been calculated in Italy at circa 2%. The state of emergency associated with the present COVID-19 pandemic has aroused the biomedical community to produce an exceptionally large number of clinical trial proposals. The World Health Organization (WHO) has accordingly addressed the challenge of promoting urgent clinical research on COVID-19 treatment while giving due consideration to the need for rigorous adherence to fundamental ethical requirements. In attempt to render the research efforts more effective an initial Core Outcome Set (COS) for clinical trials in COVID-19 has been developed and published by a Chinese group according to the Core Outcome Measures in Effectiveness Trials (COMET) handbook. Such documents provide guidance in the development of the proposed protocol in conjunction with the constraints due to the extreme circumstances imposed by the pandemic crisis.

Study Purpose	This study was designed to evaluate the safety and immunological efficacy of ArtemiC on patients diagnosed with COVID-19.
Methodology and study procedures	Single-centre open label study. 20 adult patients who suffer from severe COVID-19 infection. 10 patients received an oxygen supply before the screening. The patients were randomised 1:1. 5 patients received the study drug in addition to the oxygen therapy and 5 continued to receive oxygen. 10 patients were on a mechanical ventilation before the screening. The patients were randomised 1:1. 5 patients received the study drug in addition to the mechanical ventilation and 5 continued with the procedure of ventilation. Safety was assessed through collection and analysis of adverse events, blood and urine laboratory assessments and vital signs. After the Screening visit, the study drug will be administrated twice a day morning and evening (every 12 hours) during (day 1 and day 2)
Study Duration	The study lasts 2 weeks until conclusion on day 15 or until discharge from hospital, whichever occurs later. In case of hospital discharge within the study period, follow up will continue per protocol until day 15 wherever the subject was located. In event of a prolonged hospitalisation beyond 15 days, subjects continued to be monitored for safety and endpoints until discharge.

Inclusion/
Exclusion Criteria
	Inclusion Criteria:
	• Confirmed severe SARS-CoV-2 infection.
	• Age: 18 years old and above.
	• Subjects must be under observation or admitted to a controlled facility or hospital (home quarantine is not sufficient).
	• Ability to receive treatment by spray into the nasal cavity
	• Clinical status according to the following –
	  ○ 10 patients who need oxygen supply
	  ○ 10 patients on mechanical ventilation
	
	Exclusion Criteria:
	• Tube feeding or parenteral nutrition.
	• Uncontrolled diabetes type 2.
	• Autoimmune disease.
	• Pregnant or lactating women.
	• Any condition which, in the opinion of the Principal Investigator, would prevent full participation in this trial or would interfere with the evaluation of the trial endpoints.

Clinical Trial Results

No drug related Serious Adverse Events were obtained during the study.

The main efficacy finding which supports the clinical claim of ArtemiC, which is an anti-inflammation and immunomodulation in patients with inflammatory process, is the CRP decrease in the treatment group in comparison with the placebo.

C-reactive protein (**CRP**) is an acute inflammatory protein that increases up to 1,000-fold at sites of infection or inflammation. Having been traditionally utilized as a marker of infection and cardiovascular events, there is now growing evidence that CRP plays important roles in inflammatory processes and host responses to infection including the complement pathway, apoptosis, phagocytosis, nitric oxide (NO) release, and the production of cytokines, particularly interleukin-6 and tumor necrosis factor-α. During COVID-19 pandemic, CRP is used as one of the main prognostic factors for the clinical deterioration in hospitalized patients.

During the study, the CRP in the treatment group was decreased dramatically ($p<0.043$) in comparison with the group that received the Standard of Care treatment.