24 June 2022

ASX Code: MXC

LSE Code: MXC

ASX RELEASE

USA Market Update - CimetrA™ Clinical Trial Progress

Key Highlights:

- MGC Pharma and AMC Holdings Inc. senior executives met with University of South Florida (USF) department heads to plan the commencement of a US Clinical Trial for **CimetrA™**, supplied under the US Supply and Distribution Agreement executed in August 2021.
- The parties also advanced discussions regarding regulatory approvals for the use of MGC Pharma's leading phyto-cannbinoid medicines CogniCann and CannEpil in the USA under existing early patient access schemes.
- The US Market Access and Distribution Agreement signed with minimum orders of US$24 million for MGC Pharma products over 3 years includes CimetrA™, a plant-based Investigational Medicinal Product (IMP) currently in clinical trial phase, as a potential treatment for patients suffering from COVID-19.
- AMC Holdings is Special Purpose Vehicle founded by experienced US healthcare professionals and former federal US government officials to facilitate the research and growth of Phyto-medicines in the USA, and view MGC Pharma as a leader in the sector for the domestic market.
- AMC is responsible for managing US based clinical trials for MGC Pharma phytomedicines and for seeking US regulatory approvals including the FDA, for products which they intend to distribute in the US.
- AMC and MGC Pharma executives are currently working with University of South Florida's Botanical Medicine Research and Education Consortium to conduct the first US based clinical trial of **CimetrA™**, now scheduled begin Q3 2022 following the Company's submission of an application to the FDA as a materially advanced Investigational New Drug (IND).

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 advise that senior MGC Pharma executive directors, Roby Zomer and Brett Mitchell, are currently in the USA to meet with AMC Holding Inc. (**AMC**) and other US stakeholders to further progress the initiation of critical US Clinical Trials for MGC Pharma products covered by the US Supply and Distribution Agreement signed by MGC Pharma and AMC in 2021.

MGC Pharma and AMC executives met in Tampa with the Deans of the University of South Florida's (USF) Medical and Pharmacology School, and its Botanical Medicine Research and Education Consortium (BMER) on Thursday to confirm the timing, commitment and logistics for MGC Pharma and AMC in undertaking clinical trials based at USF. MGC Pharma's Chairman of the Board, Brett Mitchell with Managing Director and CEO, Roby Zomer held meetings at USF's Morsani College of Medicine, to discuss the first US based Clinical Trial of **CimetrA™** with BMER Director Dr. Mark Kindy, Dean Kevin Sneed, PharmD, of USF's Taneja School of Pharmacology and Dean Charles Lockwood, MD.

This US based trial will add to the clinical research on **CimetrA™** that has been carried out to date in Israel and India and will lay the foundation to achieve FDA regulatory approval for its sale and distribution in the USA as a medicine.

A Phase II double blind clinical trial in 2020 demonstrated the efficacy of the treatment for patients suffering from moderate COVID-19, with none of the patients in the treatment group requiring additional oxygen, mechanical ventilation, or admission to intensive care, in comparison with 23.4% of the placebo group requiring further assistance.

CimetrA™ is a natural medicine comprised of Boswellia and Curcumin which utilises Graft Polymer's GraftBio™ self-nanoemulsifying drug delivery system (SNEDDS).

Existing trials and observations suggest that several things distinguish **CimetrA™** as a treatment from current treatments:

- Ease of use: **CimetrA™** can be self-administered as an oral spray.
- Efficacy of the delivery mechanism: the treatment is delivered to the oral mucosal cells, where it is most efficiently absorbed into the body in a highly concentrated form, without first being degraded by amino acids in the stomach or absorbed through the stomach lining.
- **CimetrA™** is "variant agnostic": it helps the body respond to the virus infection; it is not an anti-viral, which often have more efficacy against one variant than another.
- Graft Polymer's GraftBio™ SNEDDS delivery mechanism increases the bioavailability of the active ingredients delivered to cells.
- Many patients cannot or will not take existing medications owing to contraindications or the fact that they are not considered "high risk" enough to receive the treatment. **CimetrA™** is targeting to fill that gap in the USA for healthcare providers and public health officials looking for a treatment between antivirals and infusion therapy versus "go home and let us know if you get worse."
- Cost: **CimetrA™** is selling overseas for a fraction of the cost of monoclonals and half the cost of antivirals[1].

MGC Pharma CEO and Managing Director, Roby Zomer said "*We are excited to start the trials in collaboration with USF at the earliest opportunity this year, particularly with COVID-19 spikes and new variants emerging every few months. We are looking forward to working with our US distribution partners, AMC, to bring CimetrA™ to the US market, where we believe there is a real need, and expect the treatment to be well received.*

This is an important and exciting agreement for MGC Pharma, providing access to the largest healthcare market in the world, and we are look forward to working with AMC, utilising their expertise and network to widen patient access to MGC's Phyto-medicine products."

AMC's General Counsel, Brent Yessin said "*We are fortunate to have the resources of a great research university like USF right here in Tampa and we look forward to working with Dr Kindy and Dr Sneed to get this trial underway so we can get approval for this medicine for use in our community, hopefully before the confluence of flu season and the next variant's fall arrival.*"

About AMC

AMC Holdings is a new company with expertise in healthcare and vast experience within US governmental bodies, who see Botanical and. Natural Medicines as an area of huge growth potential in the US and see MGC Pharma as a global leader in the sector.

AMC is led by CEO, Brett Scott, who spent 20 years working within the US government including the Department of Justice and US Senate. General Counsel Brent Yessin has extensive links with the healthcare industry, representing some of the largest healthcare providers and investors over the course of his time in practice. Associate General Counsel, Jim Cusack was a Partner at law firm Fowler White, and former special agent at the FBI. He was recognised by the US Drug Enforcement Agency with its Lifetime Achievement Award in 2012.

AMC's widespread networks in US government agencies and institutions as well as the Board of Directors' collective knowledge of the healthcare sector, will enable MGC Pharma products to be effectively distributed and marketed in the USA, and to find a location for the first clinical trials of MGC products in the USA.

About CimetrA™

MGC Pharma is producing, and AMC will distribute **CimetrA™** after approval by the FDA. Part of that approval process is a successful US trial demonstrating the same safety and efficacy that the European and Israeli based trials have demonstrated. USF's BMER was selected after discussions with leading research institutions around the country, as a national leader in the research and development of products that fit well with AMC and MGC's "Nature to Medicine" mission and vision.

1. www.reuters.com/business/healthcare-pharmaceuticals/price-covid-treatments-pfizer-merck-gsk-align-with-patient-benefits-report-2022-02-03/

CimetrA™ is a nano-micellular pharmaceutical synergetic composition consisting of Curcumin and Boswellia. It has antioxidant, anti-inflammatory and immuno-modulating properties, utilising self-nanoemulsifying drug delivery systems (SNEDDS).

Pre-clinical and clinical results to date support the use of **CimetrA™** as an effective treatment for addressing inflammation and cytokine over-production (known as cytokine storm) in all tested COVID-19 patients.

--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