

6 October 2021 ASX Code: MXC LSE Code: MXC

AMC USA US\$3M Purchase Order Received for CimetrA[™] including US\$1M Payment Secured for First Batch Delivery

Key Highlights:

- US\$3m (€2.6m) Purchase Order for CimetrA™ received from AMC Holdings Inc. under the 3year US\$24m US Supply and Distribution Agreement announced on 26 August 2021
- The strategic 3 year USA supply and research partnership with AMC has now been ratified
 with the receipt of the first year US\$3m Purchase Order, with payment secured for the first
 \$1m delivery to MGC Pharma with US\$375k deposit received and a US625k Letter of Credit
- AMC has also committed to provide MGC Pharma with an irrevocable US\$2m million Letter of Credit for the balance of the Purchase Order ahead of the first commercial shipment
- CimetrA™ has been proven through Clinical Trials to help treat the Cytokine Storm, a symptom of severe COVID-19
- AMC is currently working with the University of South Florida (USF) on the immediate submission of CimetrA™ to the University's Internal Review Board (IRB) as the first step towards USF joining the ongoing Clinical Trials for the Company's COVID-19 Treatment.
- AMC and USF are working towards the launch of the first US based CimetrA™ Clinical Trial and will also submit MGC Pharma's CannEpil® and CogniCann® products for approval by the IRB in the coming weeks

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 confirm that it has received a Purchase Order for US\$3m (€2.6m) from AMC Holdings Inc. (AMC) for MGC's Pharma's COVID-19 treatment, CimetrA™, as part of its three-year, US\$24m USA Supply and Distribution Agreement with the Company (refer announcement 26th August 2021). This order represents over 110,000 units of CimetrA™, the largest single order that the Company has received for any product to date, and is only for AMC's initial distribution within the State of Florida.

The US\$3m Purchase Order for CimetrA™ placed under the USA Supply and Distribution Agreement, along with the US\$1m payment secured from AMC for first order delivery with US\$375k received and a US\$625k letter of credit, is a material step forward for the Company as it starts to commercialise its clinically proven COVID-19 treatment. As part of the USA Supply and Distribution Agreement AMC is required to provide a larger Letter of Credit for the US\$2m balance of the full Year 1 purchase order value, which will be provided to MGC Pharma in the coming weeks, ahead of the first commercial supply of CimetrA™. AMC is currently in the process of securing approval for receiving CimetrA™ for distribution within the USA, which is expected take approximately 6 weeks. The USA Supply and Distribution Agreement includes an additional US\$21m of orders over years 2 and 3 for MGC products including CimetrA™, CannEpil® and CogniCann®.

As announced on 29 September 2021, AMC placed an initial order for CimetrA™, which is to be used by regulators and researchers in the US approval process. As part of this process AMC is coordinating with both the University of South Florida in Tampa, and the Holy Cross Hospital in Fort Lauderdale, to submit CimetrA™, and shortly thereafter CogniCann®, to their respective Internal Review Boards (IRB) for approval, and initiation of Clinical Trials. The approval of the respective IRBs will enable each facility to participate in ongoing Clinical Trials for CimetrA™. Once granted, the IRB approvals will also enable the hospitals to be active Clinical Trial sites for CogniCann®.



About CimetrA™

CimetrA™ is a nanoparticle micellar formulation based on the pharmaceutical synergetic composition consisting of Curcumin and Boswellia. **CimetrA™** has anti-inflammatory and immunomodulating effects and can be designed for multiple therapeutic applications utilising Graft Polymer IP Ltd's (**Graft Polymer**) proprietary GraftBioTM Self-nanoemulsifying Drug Delivery System.

GraftBio[™] is a unique platform used to deliver the natural active ingredients of **CimetrA[™]** more effectively and in higher concentrations to cells, therefore improving their bioavailability and synergy.

MGC Pharma has entered into a worldwide licensing agreement with Graft Polymer to utilise the GraftBioTM delivery system for a number of MGC products including **CimetrATM**, under which the Company pays Graft Polymer a nominal fee of €1.00 per unit sold.

Preclinical and Clinical results to date have demonstrated **CimetrA™**'s mechanism of action as an anti-inflammatory and immunomodulatory agent which is effective in the prevention of severe inflammation by its control of increased cytokine production which results from an infection of the different variants of SARS-CoV-2 (the virus responsible for COVID-19); and which is the forerunner of a Cytokine Storm, which is believed to be the main reason for mortality in severe COVID-19 patients.

The safety profile of CimetrA™ has been demonstrated during a number of *in vitro* and *in vivo* clinical trials undertaken in a GLP (Good Laboratory Practice) Accredited lab operated by Science in Action, a boutique preclinical contract research organisation located in Israel. These findings are further supported by the Phase II Clinical Trial undertaken by MGC Pharma in 2020, which demonstrated a full safety profile for CimetrA™. **CimetrA™** is currently undergoing a Phase III Clinical Trial in Israel as an Investigational Medicinal Product for the treatment of COVID-19 following successful Phase II trials in 2020. The first patient of was enrolled at the Israel trial site in July 2021.

MGC Pharma Managing Director and CEO, Roby Zomer commented: "The receipt of the first year US\$3m purchase order for CimetrA™ from AMC firmly establishes our exciting partnership and MGC Pharma's expansion into the USA market for our unique phytomedicines. The agreement will provide a foundation for further clinical research and development of our products and enable access for US patients to have access to our products in the immediate future."

Brent Yessin, General Counsel for AMC said: "The average cost of COVID-19 hospital stays in the US is \$40,000, meaning for every 1,000 patients you keep out of hospital, you save \$40 million and countless lives. Healthcare workers say they need more tools to treat people before they are so sick they need oxygen, and political leaders want to give them what they need. Helping US hospitals and physicians join CimetrATM trials in Israel and around the world is one way AMC and MGC help patients, caregivers and thought leaders gain access to those valuable tools."

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Authorised for release by the Board, for further information please contact:

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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 phyto-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 phyto-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 phyto-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 AMC Holdings

AMC Holdings, Inc. (AMC) is a privately held, US based distribution and marketing company bringing cutting edge bio-pharmaceutical products currently in clinical trials or commercial production overseas, into the US healthcare marketplace. AMC arranges for leading US researchers, academic institutions and physicians to join existing clinical trials abroad, and establish US based trials for promising bio-pharmaceutical products that meet three key criteria:

- Address disease management for pressing healthcare needs that have proven intractable and expensive employing
 existing treatments or protocols.
- Offer botanical or bio-pharmaceutical solutions where none exists, or as alternatives to existing medications with negative side effects affecting patients' quality of life; and
- Offer the prospect of expanding access to novel treatments with lower cost alternatives to existing drugs or protocols.

AMC was founded by:

- Healthcare veterans including clinicians, innovators and administrators,
- Governmental affairs specialists with decades of experience in the regulatory and political capitals throughout North America, and
- Former law enforcement officials with a proven track record of stopping dangerous drugs from reaching US cities and consumers.

AMC operates in 9 regional divisions and is actively scheduling clinical trials for MGC products in Florida, Texas and California.

AMC's Board of Directors and Board of Advisors features the DEA's Lifetime Achievement Award winner, Tampa attorney James Cusack, and former US Attorney Bobby O'Neill who once headed the Justice Department's Narcotic and Dangerous Drug Section, and attorney Joan McEnery, who worked in the White House's Office of National Drug Control Policy under President Bush.

Clinical and Research experts joining the AMC Board include former Hospital administrator and healthcare innovator Graham Russell (HCA, Ascension, Harvard Medical Group), Clinical Trial and Research veteran Paul Papagni, JD (Formerly MD Anderson, Texas Clinical Trial Network, UMD/NJ) and Global Marketing Strategists from Fortune 100 medical device manufacturers, as well as Governmental Affairs Strategists including Brett Scott (former attorney with US Justice Department and US Senate, including Senators Conrad Burns and John McCain), Beau Rothschild (Chief of Staff in the US House) and Brian Darling (Counsel and Communications Director, US Senate). Healthcare veterans Graham Russell (Surgical Services Director, Hospital Corporation of America) and General Counsel Brent Yessin, who has represented major medical centres, academic teaching hospitals and health systems around the world.



About Graft Polymer

Graft Polymer (**GPO**) is s UK incorporated holding company with innovative Research and Manufacturing Facility based in Slovenia. The core business of GPO is Polymer Modification and Drug Delivery Systems Developments.

Established in 2018, GPO have already introduced more than 50 various products to the Market: in particular- grafted polymer modifiers, nano-structured and crosslinking polymer alloys, variety of the delivery vehicles for pharma and bio applications. Graft Polymer is planning to list on the London Stock Exchange in 2021

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