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AMC Holdings orders first 1000 units of CimetrA™ to fast track USA sales and research approval processes

Key Highlights:

- MGC Pharma's distribution partner, AMC Holdings Inc, has placed an initial order for 1000 units of **CimetrA™** on an expedited basis in order to fast track the approval process for the medication to be distributed and sold in the USA
- AMC is working with the University of South Florida (USF) on the immediate submission of **CimetrA™** to USF's Internal Review Board (IRB) due to the continuing COVID-19 crisis in the US
- This is the first step towards adding the University to the ongoing clinical trials for **CimetrA™**, with AMC and USF working towards a launch of the first US based Clinical Trials shortly thereafter. AMC will also submit **CannEpil®** and **CogniCann®** for approval by the IRB in the coming weeks
- AMC is submitting both **CimetrA™** and **CogniCann®** to the IRB of the Holy Cross Hospital in Fort Lauderdale, Florida. The approval by the IRB will begin the process of the hospital's participation in the Clinical Trial process for **CimetrA™**, and will serve as an active site for **CogniCann®**
- US based Clinical Trials are being established for MGC Pharma's phytomedicine products in Florida, Texas, the NYC area, and Kentucky, and are expected to commence in Q4 2021
- **CimetrA™** has been proven through Clinical Trials to help treat the Cytokine Storm, a symptom of severe COVID-19

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 an update on material progress being made in the USA in recent weeks, on both research, and commercial activities under the Supply and Distribution Agreement (**US Supply Agreement**) signed with AMC Holdings Inc (**AMC**) in August of this year (refer announcement dated 26th August 2021).

AMC has now formally submitted an initial order for 1000 units of **CimetrA™** on an expedited basis, which are to be used by regulators and researchers to fast track the approval process in the US. The units will be shipped to a Tampa area pharmacy where they will be analysed in order to make comparisons (in consultation with the clinical staff) with MGC Pharma's research lab in Slovenia, and will be held for research and regulatory purposes.

This process is the first step to undertaking the first material commercial order of MGC Pharma products as contemplated under the US Supply Agreement signed by the parties in August 2021. Both parties are working together in order to meet the key conditions of the US Supply Agreement to formalise the business and research partnership as contemplated and set out in the announcement on 26 August 2021, and are confident they remain on track to do so.

Clinical Research Programs with University of South Florida

AMC is currently working 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. The approval from these boards is the first step for both facilities to join the Clinical Trials which are underway in Israel, and to launch US based Clinical Trials for **CimetrA™** and **CogniCann®**. The University of South Florida is a public university

with over 40,000 students, a top 50 medical and pharmaceutical research facility in the USA, and undertakes valuable collaboration with the Veteran's Administration.¹ The Holy Cross Hospital, located in the Miami-Dade/Broward/Palm Beach healthcare market, works in collaboration with Massachusetts General Hospital, Harvard University's teaching hospital.²

Further to the proposed research development at USF and Holy Cross Hospital, AMC is working to establish a number of US based Clinical Trials for MGC Pharma's products, including **CimetrA™**, **CannEpil®** and **CogniCann®** in Florida, Texas, the New York City area, and Kentucky.

MGC Pharma CEO and Managing Director, Roby Zomer, commented: "AMC are already making significant progress in propelling CimetrA™, CannEpil® and CogniCann® to Clinical Trial stage in the US and we are pleased that they have cemented relationships with these prestigious institutions for the continued research into our products."

Brent Yessin, General Counsel for AMC said: "As the US endures a COVID spike, keeping COVID positive patients out of the hospital has become a major policy objective of countless state Governors and their health departments. For every 1000 patients who are treated effectively and kept out of hospital, the state or healthcare systems save US\$40M, a rare instance where clinical and financial imperatives are perfectly harmonized."

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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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¹ Source: <https://www.usf.edu/news/2021/usf-graduate-programs-among-the-nations-best-in-new-rankings-by-us-news-world-report.aspx>

² Source: <https://southfloridahospitalnews.com/holy-cross-health-announces-strategic-collaboration-with-massachusetts-general-hospital/>