

20 October 2022

ASX Code: MXC

LSE Code: MXC

Operations Update – Major Milestones Achieved

Key Highlights:

- Processing upgrade to Slovenian compounding facility completed, increasing daily production capacity by 200%.
- EU Good Manufacturing Practice (GMP) audit for the Slovenian production facility completed in October, including approval to re-commence production, with formal certification expected in November.
- GMP audit of MGC Pharma’s new Maltese GMP production facility has satisfied all key audit requirements, and is expected to be formally certified in early 2023.
- MGC and Sciensus Rare’s Supply and Distribution Agreement expanded to include new European markets, and Middle Eastern territories, increasing the potential market for **CannEpil®** and **CogniCann®**.
- MGC fast tracks production in order to deliver 50,000 units of **ArtemiC™** Rescue to AMC Holdings in a single shipment, with AMC experiencing higher demand than anticipated.

MGC Pharmaceuticals Ltd (‘MGC Pharma’ or ‘the Company’) a European based bio-pharma company specialising in the production and development of plant inspired medicines, is pleased to provide an update on its operations.

EU GMP Production Facilities

The upgrade of MGC Pharmaceutical’s GMP certified production facility in Slovenia has been completed, with formal EU GMP re-certification to be finalised in November. Following the facilities upgrade, the plant’s production capacity has been increased by 200%, and with the recommencement of production at the facility approved by the regulatory authority, the facility is back in production. The recommencement of production at MGC’s Slovenian production facility, which has been undertaking a production upgrade over the past months, will enable MGC to meet increasing demand for its cannabinoid medicine products alongside its ongoing clinical trials.

Further to this, the audit of the Maltese GMP facility has been completed and critically met all key GMP audit criteria. As a result, formal EU GMP certification as a production facility is now expected in early 2023, at which point the Company will have two, high-quality, EU GMP certified production facilities from which it will be able to manufacture and distribute its proprietary IMP products **CimetrA™**, **CannEpil®** and **CogniCann®** across the EU, and globally.

A separate audit and inspection of both facilities has been undertaken by MGC’s distribution partners, including Sciensus Rare, as part of their Quality Assurance process, ensuring that the facilities will be able to begin taking commercial orders for MGC Pharmaceutical’s products produced in either facility for distribution across each partner’s respective networks.

Sciensus Rare distribution network expansion

MGC is pleased to announce that MGC Pharma’s partnership with Sciensus Rare has been expanded to cover additional territories across Central and Eastern Europe, along with the Middle East and North Africa. This expanded remit, and the subsequent opening of early access into untapped markets will enable MGC Pharma to achieve its goal of delivering proprietary IMP products **CannEpil®** and **CogniCann®** to the new markets in order to help treat patients with severe medical needs.

A
S
X

R
E
L
E
A
S
E

AMC Holdings contract update

AMC Holdings, MGC Pharma's US-based distribution and marketing partner, is amending the terms of its US\$1,000,000 order of ArtemiC™ Rescue, with the product now to be delivered in a single shipment, rather than multiple shipments, so that it is ready for immediate supply to the US owing to increasing demand.

MGC Pharma Managing Director and CEO, Roby Zomer commented: *"Following the completion of the GMP and customer audit of the Company's Slovenian GMP Production facility, following the recent production capacity upgrade, MGC Pharma is extremely well placed to deliver its products across both the EU, and globally, to meet increasing demand. This will be further enhanced by the formal GMP certification of MGC's Malta facility, which is now forecast to occur in early 2023.*

What is clear from our discussions with both Sciensus Rare and AMC Holdings, is that demand for our products is strong, and it is important that the business is well positioned to service this demand, both in terms of our production capacity, and the progress of our products through the clinical pipeline."

--Ends--

Authorised for release by the Board, 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 Financial and Corporate Advisor

Hannam & Partners
Rupert Fane / Nilesh Patel
+44 7810 056 104
rf@hannam.partners / nilesh@hannam.partners

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, focused on developing and supplying accessible and ethically produced plant inspired medicines, combining in-house research with innovative technologies, with the goal of finding or producing treatments to for unmet medical conditions.

The Company's founders and executives are key figures in the global pharmaceuticals industry and the core business strategy is to develop and supply high quality plant inspired medicines for the growing demand in the medical markets in Europe, North America and Australasia.

MGC Pharma has a robust development pipeline targeting two widespread medical conditions and has further products under development.

MGC Pharma has partnered with renowned institutions and academia to optimise the development of targeted plant inspired medicines, to be produced in the Company's EU-GMP Certified manufacturing facilities.

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    

About AMC Holdings, Inc.

AMC Holdings, Inc. 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 Sciensus Rare

Science International B.V. trading as Sciensus Rare, is the dedicated and enhanced rare disease medicines service business within the Sciensus group of companies, the largest speciality pharmacy provider in Europe, of complex medication management in a home environment.

Sciensus Rare is a speciality pharmacy focused on rare diseases, providing turnkey services for emerging and medium-sized biotech organisations, achieving market access for their products in Europe and beyond. Sciensus Rare offers five main services; decentralised clinical trials, medicines access, tailored supply chain management, patient and family support and outcome monitoring.

www.sciensus-rare.com