22 January 2019

ASX Code: MXC

Major Regulatory Milestones Achieved for Pharma Business

- TGA has approved TGO93 Declaration Form, advising that our CTN (Clinical Trial Notification) for CogniCann™ into Alzheimer's and dementia at the University of Notre Dame has been processed and is available in the Clinical Trials Repository
- Government approval for API Extraction at MXC's European Facility - now one of the first EU facilities to be granted a full API extraction permit, issued by the Slovenian Ministry of Health. MXC can now develop its own THC, CBD and other Phytocannabinoids as API's for the formulation of CannEpil™, CogniCann™ and future phytomedicines
- SME certification issued by the European Medicines Agency (EMA); providing access for scientific advice, drug evaluation and registration of CannEpil™, CogniCann™ and additional Phytomedicines that the Company is developing. It also provides MXC the opportunity to obtain fee reductions up to 100% in the development and registration of priority medicines (PRIME)
- Each achievement delivers on the Board's strategy and commitment to the growth of MXC's pharma business and demonstrates the Company's progress to deliver near-term commercial outcomes on its seed-to-pharma strategy

MGC Pharmaceuticals Ltd (ASX: MXC or "the Company") is pleased to announce its pharma business has achieved a number of key milestones for its European and Australian manufacturing and research operations over recent weeks, that materially advances the Company towards commercialisation and delivering on its seed-to-pharma business strategy. These results deliver real outcomes and major milestones from the excellent work of the Company's management and its employees, and executing the vision of building a leading European bio-pharma company for all MXC shareholders.

TGA approval for CogniCann™ use during clinical trial

In a major achievement for its product development pipeline, the Company has received formal approval by the TGA for our TGO93 Declaration Form, informing that our CTN (Clinical Trial Notification) has been processed and is now available in the Clinical Trials Repository. The approval allows MGC to initiate its Phase IIB Clinical Trial on Dementia and Alzheimer patients with UNDA in WA, and start the recruitment of patients, using its second GMP certified IMP (investigative medicinal product) CogniCann™.

info@mgcpharma.com.au | mgcpharma.com.au
MGC Pharmaceuticals Ltd | 1202 Hay Street, West Perth, WA 6005
PO Box 1976, West Perth WA 6872
T: +61 8 6382 3390

The trial has been approved by the Human Research Ethics Committee and will focus on the effects of the medicinal cannabis treatment on the symptoms of mild dementia and Alzheimer's and the improvement of patient's quality of life, at the University of Notre Dame, Western Australia.

Receipt of TGA approval signals the start of patient recruitment and the 16-week trial remains on track to commence in H1 2019.

During the trial, CogniCann™ specifically formulated by MXC, will be tested on a total of 50 patients aged 65 and over, alongside a series of pre and post-treatment surveys and focus groups that will be used to assess the effects of the product.

Government Approves European Manufacturing Facility for Extraction of Phytocannabinoid API

In a significant operational milestone for the Company to be one of the only in the EU today, MXC has received a permit from the Slovenian Ministry of Health granting it with permission to operate its Phytocannabinoid extraction at its Manufacturing Facility in Ljubljana, for the purposes of;

1. Development of new formulations with Phytocannabinoids coming from different genetics to gain different and new natural API
2. Development of own Phytocannabinoids (THC, CBD, etc.) active ingredient API (Active Pharmaceutical Ingredient) from cannabis plants
3. Optimize and validation of the extraction and isolation process with the purpose of control and understanding of all components

MXC's is one of the first European Union facilities to receive permission to extract and develop its own natural Phytocannabinoid API at its European manufacturing facility, delivering the Company a significant edge towards the full vertical integration for production of its own bio-pharma products. All findings and intellectual property from the process will be used to formulate the future pipeline of the Company's phytomedicines.

This is a landmark milestone for MXC, as the company can now produce its API's in house at a very low cost base for its own Phytomedicine production, delivering vertical integration in the whole value chain to produce high margin, affordable medicine products for sale. Furthermore, it will allow MXC to develop new formulations based on new Phytocannabinoids which are not available in the market as API and will give the company the edge in better, more efficient Phytomedicines formulations.

Receipt of this permit illustrates further progress as the Company moves towards final stages of seed-to-pharma phytomedicine development and the Company's ability to commercialise medicinal cannabis treatments globally.

MXC receives SME qualification from European Medicines Agency

In a recent international achievement, MXC was the first Australian Medical Cannabis company to receive SME qualification from the European Medicines Agency (EMA) for all of the company's Phytomedicines – the European equivalent to the TGA in Australia and the FDA is the USA.

This qualification means the Company has access to EMA's SME user guide, designed to help enterprises navigate regulatory requirements and incentives available throughout a medicine's product lifecycle. The guide also provides an overview of procedures to support research and development initiatives and explains the requirements to successfully obtain marketing authorisation.

Additionally, SME registration allows the Company to apply for scientific advice, drug evaluation and registration of CannEpil™, CogniCann™ and all other Phytomedicines currently under development. This is in addition to the opportunity to obtain fee reductions of up to 100% during the evaluation and registration process of priority medicines (PRIME).

Receipt of this qualification represents a milestone for the Company's European operations and strengthens its GMP certified Phytomedicines product pipeline demonstrating the Company's ability to commercialise and deliver on its European based, seed-to-pharma strategy.

MXC's Scientific Advisory Board to present at CannaPaed Symposium 2019

The Senior Management and Scientific Advisory Board are in the final stages of preparation to present at the CannaPaed Symposium 2019, for the second time.

The CannaPaed Symposium 2019 will be held on the 25th January 2019 in Ljubljana, Slovenia and is intended for anyone taking care of children. The conference is focussed on children with drug resistant epilepsy as well other medical conditions such as dystonia, autism or cancer, that could benefit from medicinal cannabis treatments.

The event will be hosted by Professor David Neubauer and Roby Zomer and will be presented by MXC's Professor Uri Kramer and CSO Jonathan Grunfeld. The presentations will be focussed on the shift from traditional to Phytomedicines and the potential benefits to patients within drug resistant conditions.

Brett Mitchell, Executive Chairman, MGC Pharmaceuticals commented

"The achievement of these major milestones by our team demonstrates significant progress on MXC's pathway to commercialisation and is testament to the Board's commitment to building a strong, vertically integrated company under its seed-to-pharma strategy. We are now one of the leaders in Europe in our sector."

"The progress within our pharma business is evidence of the dedicated work behind the scenes from the entire MXC team and we expect 2019 to deliver significantly more growth and ongoing development."

Roby Zomer, Co-founder and Managing Director, MGC Pharmaceuticals commented

"We are extremely excited to see our European operations progressing so considerably, especially the expansion of our R&D capabilities. Research and innovation are the lifeblood of the pharmaceutical industry and we are working hard to not only build a growing company but bring effective treatments to patients."

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For further information, please contact:

Media Enquiries
Justin Kelly
Media and Capital Partners
+61 408 215 858
Justin.kelly@mcpartners.com.au

MGC Pharmaceuticals Ltd
Brett Mitchell
Executive Chairman
+61 8 6382 3390
info@mgcpharma.com.au

About MXC

MGC Pharmaceuticals Ltd (ASX: MXC) is an EU based Bio-Pharma company with many years of technical clinical and commercial experience in the medical cannabis industry. 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 Cannabinoids based pharmaceuticals products for the growing demand in the medical markets in Europe, North America and Australasia.

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