

27 August 2018

ASX Code: MXC

Ethics Approval received for Australian Phase II Clinical Trial into Dementia

*MXC to test GMP Cannabis formulation on Dementia conditions
with University of Notre Dame*

- In partnership with the Institute for Health Research at the University of Notre Dame, MXC received Human Research Ethics Committee approval to conduct a Phase II clinical trial into the benefits of CogniCann™ in Dementia and Alzheimer patients.
- CogniCann™ is one of MXC's medical cannabis pharmaceutical products with a THC:CBD ratio specifically formulated for the treatment of key Dementia symptoms and improving specific cognitive functions
- The Western Australian based trial is expected to commence in early 2019
- Leverages the key IP secured through MXC's Medical Advisory Board of world experts, led by renowned Professor Uri Kramer
- Marks another landmark achieved for MXC's pharmaceutical product development pipeline and cements the Company's seed-to-pharma business model

MGC Pharmaceuticals Ltd (ASX: MXC or "the Company") is pleased to announce it has been granted full Ethics approval to conduct a Phase II clinical trial into the effects of CogniCann™, a GMP certified, pharmaceutical grade medicinal cannabis compounded formulation, on patients with mild Dementia and Alzheimer's.

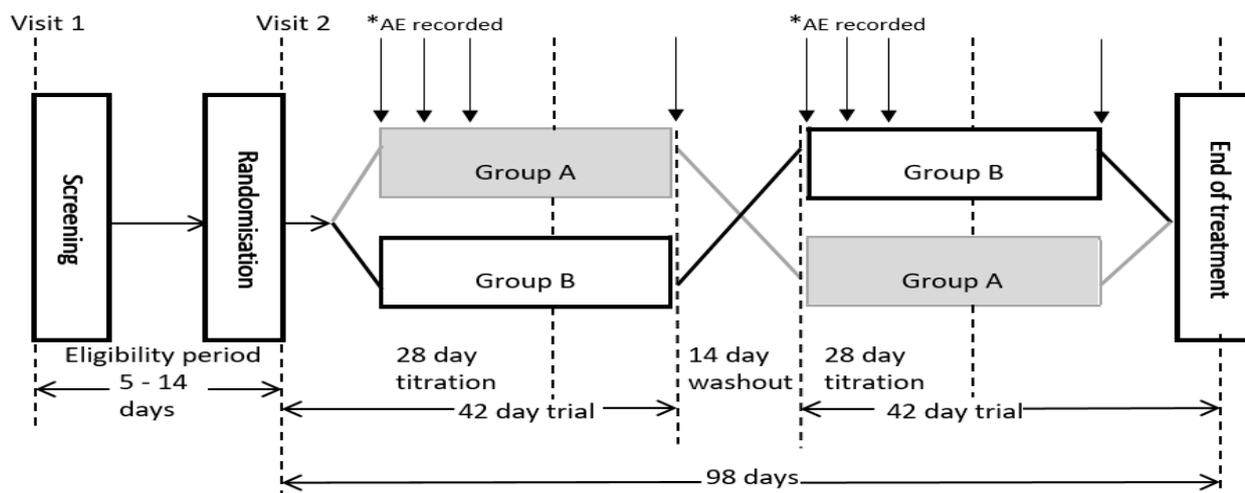
Approval follows the successful completion of a full ethical review undertaken by the Human Research Ethics Committee (HREC) at the University of Notre Dame in Western Australia (UNDA), in accordance with the National Statement on Ethical Conduct in Human Research.

The 16 week trial will be undertaken by the University's Institute for Health Research and is expected to commence in early 2019, subject to TGA approval, using a randomised, double-blind, crossover, placebo-control design to evaluate the behavioural changes, quality of life, and level of discomfort and pain in Dementia patients living in residential aged care facilities.



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*Adverse events (AE) will be recorded with each dose increase during the titration phase and on the last dose during the intervention phase

MXC Launches New GMP Certified Medicinal Cannabis Formulation

GMP certified medicinal cannabis medicine, CogniCann™ specifically formulated by MXC, will be tested on a total of 50 participants aged 65 years and older. This will be performed alongside a series of pre and post-treatment surveys and focus groups that will be used to assess residential staff and family member’s knowledge and perceptions towards the use of the treatment.

The trial has been designed by MXC’s expert Medical Advisory Board led by Professor Uri Kramer and the research team at UNDA, where health and medical research was rated as above world standard in the recent “Excellence in Research for Australia” (ERA) 2015 assessment process. The team has extensive experience in conducting and analysing complex clinical trials.

On completion of the trial, MXC will own all IP and results and the researchers will acquire a worldwide non-exclusive, royalty free licence to use the project’s Intellectual Property for non-commercial research purposes including research publications.

This represents a milestone for MXC, which is on the road to becoming a bio-pharmaceutical company with a library of medicinal cannabis formulations that have been compounded into final medications for the treatment of a wide range of indications. MXC’s range of GMP certified pharmaceuticals are engineered and produced within its EU production and manufacturing facility supporting the business model of having seed-to-pharma operations.

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

“We are pleased to have received ethics approval for our Phase II clinical trial assessing the effects of our medicinal cannabis medicine, CogniCann™ on patients with mild Dementia and are excited to start working with the superior team of researchers at the University of Notre Dame.”

“We are building strong relationships in the medical research industry and see this as taking the next step in our strategic growth and development of our seed-to-pharma capabilities.”

Professor Jim Codde, Director Institute for Health Research, The University of Notre Dame Australia commented:

“Health research, especially into issues affecting those most in need within our community, is of the highest priority to Notre Dame. Research initiatives into Dementia is also a national priority so we are very excited to work with MXC and the aged care sector to trial this novel approach to improve the quality of life for the almost 350,000 Australians suffering this disease that currently has no cure.”

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About MXC

MGC Pharmaceuticals Ltd (ASX: MXC) is an EU based BioPharma 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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