

9 March 2020  
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## First Australian patients begin treatment in Phase II clinical trial of CogniCann®

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ANNOUNCE

**MGC Pharmaceuticals Ltd (ASX: MXC, 'MGC Pharma' or 'the Company')**, a European based 'Seed to Medicine' bio-pharma company specialising in the production and development of phytocannabinoid-derived medicines, is pleased to announce that the first patients will begin treatment today in MGC Pharma's Phase II Clinical Trial in partnership with the University of Notre Dame Australia in Perth, Western Australia ('UNDA') ('the Trial'). The Trial will evaluate the effects of CogniCann®, which has been developed with the specific aim to treat the symptoms associated with dementia and Alzheimer's disease by the Company's Clinical Advisory and Research team. This follows the first bulk shipment of CogniCann® to Australia in December 2019.

### Key Highlights:

- The Phase II clinical trial, which commences today, is to evaluate the potential behavioural benefits CogniCann® may have on patients with dementia and Alzheimer's disease
- The Trial will involve a total of 50 patients, aged 65 and older, from various aged care facilities in Perth, Western Australia
- New patients are expected to commence treatment each week, with the Trial lasting 18 weeks per patient
- Results of the trial are conservatively expected by the end of Q3 2021
- The Trial is looking to confirm the clinical efficacy of the drug (CogniCann®) and determine the therapeutic individual dose response
- The Trial is a randomised double blind, crossover, placebo-controlled clinical trial
- CogniCann® is also now available for prescription in Australia under the Special Access Scheme through the Company's distributors, Health House International and Cannvalate
- It is estimated that nearly 500,000 people in Australia suffer from Alzheimer's disease, with approximately 80% having mild or moderate symptoms<sup>1</sup>. In Europe, this number is closer to 1.5 million and is expected to grow by 15% by 2024<sup>2</sup>
- CogniCann® is currently the only dementia targeting phytocannabinoid-derived product available for prescription in Australia, putting the Company in a unique position to access a large patient population in Australia and key international markets via early access schemes

**Roby Zomer, Co-founder and Managing Director of MGC Pharma, commented:** "I am proud to see the commencement of this Phase II clinical trial in partnership with UNDA. The Trial will provide the healthcare community with more evidence on the performance and the benefits of phytocannabinoid-derived medicines, in particular for patients suffering from dementia and Alzheimer's disease, and we hope to see positive results in the near future. If successful, CogniCann® has the potential to positively impact the lives of patients and their carers around the world, and contribute to a novel avenue of clinical research and development for contending with the challenges of the effects of dementia and Alzheimer's disease.

"We are privileged to work with such an esteemed medical institution as UNDA and its research team, that was rated as at world standard in the "Excellence in Research for Australia" 2018 assessment process. I look forward to updating the market on progress of our Trial."

<sup>1</sup> Source: Alacrita Research Report: Market Projections October 2019

<sup>2</sup> Source: Alacrita Research Report: Market Projections October 2019

**Professor Uri Kramer, Member of MGC Pharma Clinical Advisory Team, commented:** “The number of dementia patients with various behavioural difficulties is growing globally. We have designed a phytocannabinoid derived medication with a ratio of cannabinoids that we hope to demonstrate is appropriate for treating this unique group. Through this study, we hope that in the near future we can offer patients with dementia an effective medication that will significantly improve their quality of life.”

**Dr Amanda Timler, Principal Investigator, UNDA, commented:** "We are excited to begin treatment with our first group of participants to assess the clinical efficacy of CogniCann® to improve the quality of life of those living with dementia."

#### **Additional Information**

The purpose of the Trial is to confirm the clinical efficacy of the drug and determine the therapeutic dose range. It will be conducted by the UNDA, with various aged care facilities in Perth. The Trial involves 50 patients aged 65 and over and is a randomised double blind, crossover, placebo-controlled clinical trial.

The Trial will be performed alongside a series of pre and post survey responses and focus groups that will be used to assess care givers and family member’s knowledge and perceptions towards the use of the treatment.

Staged enrolment of participants will mean the study will run for over a year with each participant being involved for 18 weeks. The Trial has been designed jointly by MGC Pharma’s expert Clinical Advisory Team led by Professor Uri Kramer and the research team at UNDA, whose health and medical research was rated as at “world standard” in the “Excellence in Research for Australia” 2018 assessment process.

On completion of the Trial, MGC Pharma will own all Intellectual Property (IP) and results and the researchers will acquire a worldwide nonexclusive, royalty free licence to use the project’s IP for non-commercial research purposes including research publications.

CogniCann® is also now available for prescription in Australia under the Special Access Scheme through the Company's distributors, Health House International Pty Ltd and Cannvalate Pty Ltd which is expected to bring additional revenue to the Company both in Australia and key international markets during 2020.

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## About MGC Pharma

MGC Pharmaceuticals Ltd (ASX: MXC, OTCQB: MGCLF) 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 'Seed 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 recent research conducted in collaboration with the National Institute of Biology and University Medical Centre Ljubljana, highlighted the positive impact of using specific phytocannabinoid formulations 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. In order to meet the demands of becoming a key global supplier the company is constructing a 15,720m<sup>2</sup> GMP state of the art facility in Malta.

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