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MGC Pharma 2021 Clinical Trials Program Update on CimetrA™, CannEpil® and CogniCann®

Key Highlights:

- MGC Pharma's major clinical trial program for 2021 continues to progress, including imminent commencement of CimetrA™ Phase III and CannEpil® Phase IIb trials.
- All the required regulatory approvals have now been received for both the CimetrA™ Phase III and CannEpil® Phase IIb clinical trials.
- An application has also been submitted to the Brazilian regulatory agency, ANVISA, to add an additional eight clinical sites to the CimetrA™ Phase III trial.
- The first patients are expected to be enrolled in June 2021 for the Phase III CimetrA™ and September 2021 for the Phase II CannEpil® Epilepsy trial.
- Interim trial results are expected in Q3 2021 for CimetrA™ and Q4 2021 for CannEpil® .
- An additional trial focused on the safety of CannEpil® was approved and initiated in Australia, with the first patient (of 31) is expected to be recruited in June 2021.
- Phase II clinical trial for CogniCann® at the University of Notre Dame, Perth has already recruited 21 of 50 patients and interim results are expected in Q4 2021.
- All three trials are well funded following the successful £6.5 million IPO fundraising and listing on the London Stock Exchange in February 2021.

MGC Pharmaceuticals Ltd (ASX, LSE: MXC, 'MGC Pharma' or 'the Company'), a European based bio-pharma company specialising in the production and development of phytocannabinoid-derived medicines, is pleased to provide a progress report on its major clinical trial programs planned for 2021, which are actively progressing across Australia, Israel and Brazil.

CimetrA™ - Phase III controlled clinical study

MGC Pharma's phase III clinical trial has been designed to evaluate the efficacy and safety of CimetrA™ as a treatment for hospitalised patients diagnosed with COVID-19, and to provide additional data for claims on the product as an Investigational Medicinal Product (IMP). The trial will enrol a total of 252 patients and will be conducted over a 28-day period.

The Israeli Ministry of Health approval has now been received and the trial will shortly be initiated at the two clinical sites, Rambam Health Care Campus and Nazareth Hospital EMMS in Israel. This follows receipt of ethics committee approval in March 2021 (see ASX announcement 23 March 2021). The first patient is expected to be enrolled during June 2021, following the completion of CimetrA™ IMP Production and validation (from supplement production).

The Company intends to expand this trial to strategic global jurisdictions, and as such has submitted an application for eight additional clinical sites in Brazil. MGC Pharma is working with the Brazilian regulatory agency, ANVISA, in order to obtain the final approvals required to progress with the study. The first patient in Brazil is expected to be enrolled in July 2021.

The recent delay in the enrolment of the first patient due in for the Phase III trial is a result of logistical issues surrounding obtaining bulk supply of a key ingredient for CimetrA™ owing to the COVID-19 outbreak. It has not affected the continued development of the drug which has continued parallel to the Phase III trial planning.

Interim results of the trial are expected to be released in August 2021 and the trial is expected to complete with final results due in Q4 2021.

CannEpil® (MGCND00EP1) – Phase IIb randomised, double blind, placebo controlled clinical study

The phase IIb clinical trial will take place at the Schindler Hospital in Israel and will focus on the safety and efficacy of CannEpil® as an add-on treatment in children and adolescents with treatment resistant epilepsy, also known as refractory epilepsy. A total of more than 100 patients will be recruited into the trial.

The study drug import process has commenced following Israeli Ministry of Health approval. The trial will be initiated in July and the first patient is expected to be enrolled in September 2021. Interim results of the trial are expected in Q4 2021.

MGC has already initiated a Driving Safety study of CannEpil® in Australia following the reopening of universities after the COVID-19 lockdowns. This trial involves healthy volunteers and aims to demonstrate the safety of CannEpil® in order to provide supportive data to the regulatory authorities.

The first patient is expected to be recruited in June 2021 and 31 patients are expected to be recruited in October 2021.

CogniCann® – Phase II clinical trial

The Phase II clinical trial at the University of Notre Dame in Perth, Western Australia has been designed to evaluate the potential behavioural benefits of CogniCann® on patients with dementia and Alzheimer's disease. The trial will enrol 50 patients and is expected to last until Q4 2021.

Initial recruitment commenced in January 2020 but was temporarily suspended due to the COVID-19 restrictions in WA. Recruit has recommenced and 21 patients have been enrolled in the trial over the last three months. Interim results are expected to be released in Q4 2021.

All three trials are well funded, following the successful £6.5 million IPO fundraising and listing on the London Stock Exchange in February 2021, and the Company will make further updates on them in due course.

Roby Zomer, Co-founder and Managing Director of MGC Pharma, commented: "All of our clinical trials are progressing well despite the various hurdles we are facing due to the current global situation. These trials ensure MGC Pharma and our product offering realise their full medical and commercial potential as we focus on creating new and effective treatments for conditions and diseases that currently have no treatment options."

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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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