27 July 2020
ASX Code: MXC

Results received from ArtemiC safety and toxicity pre-clinical study

ASX RELEASE

Key Highlights:

- Safety and toxicity pre-clinical study results have been received by MXC for ArtemiC following *in vivo* testing on mice in Israel, with ArtemiC delivering no adverse results in standard toxicity measures
- Nine mice across three study groups were tested with 25ul, 50ul doses (comparable to more than 100 times the dose being used in the current clinical trial) and a control group to assess the safety and toxicity of the treatment on the cells
- ArtemiC is designed with the scientific aim to target viral infections with inflammatory complications which is currently being evaluated in a Phase II clinical trial on novel coronavirus 2019 (SARS-CoV-2) infected patients
- These results support the ArtemiC treatment regimen defined in the current Phase II clinical trial in COVID-19 patients and these data will be used for future clinical studies
- Additional histology test results analysing the impact of ArtemiC on major organs from this pre-clinical study on mice are expected within the coming days

MGC Pharmaceuticals Ltd (ASX: 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 announce it has received results from a safety and toxicity study completed on mice for ArtemiC showing no clinical signs or adverse reactions from the full panel of hematology and chemistry blood tests. The results are promising and confirmed that ArtemiC was administered safely in animal models in two separate doses. This pre-clinical study on ArtemiC was performed in the Science in Action Laboratory in Ness Ziona, Israel. ArtemiC is a natural supplement formula based on Artemisinin and Curcumin (along with supporting ingredients Vitamin C and *Boswellia serrata*) well-known natural active ingredients with anti-infective properties, as detailed in ASX release on 17 April 2020.

This is a promising study outcome for the Company and its ongoing clinical trial and studies on ArtemiC. The Company now expects to receive histology test results analysing the impact of ArtemiC on major organs from this same study on mice within the next coming days.

The pre-clinical study was completed on nine mice in three study groups, with three mice per group. The mice in each group were given either 25ul, 50ul or none (the control group) and the mice were observed and tested for clinical changes over seven days. This study was conducted as a non-GLP (Good Laboratory Practice) study as GLP regulation for this type of study is not required or mandatory for product registration and the FDA does not require GLP for safety *in vivo*. Full details on the study required for compliance with the ASX Code of Best Practice for Reporting by Life Science Companies are included in Annexure A.

Ongoing Phase II clinical trial on novel coronavirus 2019 (SARS-CoV-2) infected patients

These results support the ArtemiC treatment regimen defined in the current Phase II clinical trial in COVID-19 patients and these data will be used in any future clinical studies.

The Phase II clinical trial that commenced in Israel at the Nazareth Hospital EMMS and Hillel Yaffe Hospital in May 2020 is progressing on schedule. The significant spike in COVID-19 infection rates in Israel over the past 6 weeks has led to an increase in patient recruitment applications and the COVID-19 infected patient pool. The first interim results from the COVID-19 infected patients are expected to be available to the Company by early August.

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The Phase II clinical trial at the Mahatma Gandhi Mission's Medical College & Hospital in India (announced 2 July 2020) is also moving forward, with the first patient expected to commence treatment in the coming 1-2 weeks. The significant infection rate increase in India during June and July created strong support from the government for the fast tracking of the trial.

As the next stage of the study will be Phase IIb (which will include dosage analysis), it is important to know the maximum dose we can increase from the treatment being tested today in our current Phase II trial (Efficacy and Safety assessment). Therefore, the safety assessment in this pre-clinical study on mice is critical for understanding and calculating the increased dosage limits without risking patients' lives, as such the results are critical. Furthermore, although it is not mandatory, as part of this pre-clinical study we need to know the impact on the animal brain and lung histology (as COVID-19 targets organs), as this will be the base to increase the dose finding in cases that are more difficult to treat if needed.

Roby Zomer, Co-founder and Managing Director of MGC Pharma, commented: "We are very pleased with these results achieved in the ArtemiC safety and toxicity study. Importantly, this study provides further support for the parameters of our Phase II clinical trial in COVID-19 patients currently underway. We look forward to receiving the histology results from this *in vivo* study in the coming days, to be followed by the first interim results from our Phase II clinical trial in Israel on COVID-19 infected patients that are now expected by early August."

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About MGC Pharma

MGC Pharmaceuticals Ltd (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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ANNEXURE A

The ArtemiC animal study was performed in the Science in Action Laboratory in Ness Ziona, Israel, under Ethics Committee Approval Number IL-20-6-283.

Science in Action is accredited for OECD principles of Good Laboratory Practice ENV/MC/CHEM (98)17 for toxicity studies; however, this study does not follow the complete GLP regulations, and is thus considered a non-GLP study. The study follows this protocol and the Science in Action SOPs. The FDA does not require GLP for safety in vivo. As it is not mandatory to be under GLP therefore it was decided there was no clinical or regulatory reason to do GLP on this study.

The main goal of the trial was to evaluate the safety and toxicity of ArtemiC in animal model. 9 Balb/c mice, 8 weeks old, body weight 19-21 g were used for the experiment. In each group 3 mice were treated in splash route of administration into the oral cavity on day 1 with the experimental drug according to the randomization group. Each animal was weighed prior to treatment.

Study groups -

Group 1 (n=3): 25ul /mouse

Group 2 (n=3): 50ul /mouse

Group 3 (n=3): Control group

In order to track the side effects and toxicity of the tested substances, the animals were observed during all 7 days of the trial for abnormal clinical signs.

After 7 days blood samples from all mice were taken for a full panel of hematology and chemistry blood tests. After blood collection the animals were sacrificed and the organs: brain, lungs, heart, liver, spleen and kidneys were removed and kept in formalin 4%, and were sent for pathological examination.

Results

No clinical signs were observed in the animals.

No difference between study groups (treatment arms versus placebo) was observed in the mice weight, organs (brain, lungs, heart, liver, spleen, kidneys) weight. The blood tests did not demonstrate variability between study groups (treatment versus placebo).

Based on the results we can conclude that ArtemiC was found safe in animal models in two doses. These results will support future efficacy clinical studies in Phase IIb and III in COVID-19 patients. Phase IIb study will include efficacy endpoints and dose finding elements, based on the current animal study results. Current study results support the ArtemiC treatment regimen defined in Phase IIa clinical study in COVID-19 patients and will be used in the future clinical studies.

This is the first *in vivo* safety test on this combination of ingredients and delivery system, which we need for the Phase IIb and for the FDA submission, it was very important to see that even on the double dose the product remained in the safe value.