14 October 2020

ASX Code: MXC

ArtemiC™ *in vivo* histology results on rats confirm no pathological impact on major organs

ASX RELEASE

Key Highlights:

- Following the safety and toxicity testing completed on mice (refer ASX release 27 July 2020), MXC completed the next phase of pre-clinical *in vivo* safety and toxicity testing of ArtemiC™ on twenty-four rats showing no adverse results in standard toxicity measures
- Histology results received from the rats show no pathological changes in all tested animal samples
- This is important as this test completes the FDA requirements for toxicology tests for new drug development. The results show the safety and tolerability of ArtemiC™ in two rodent studies under very strict requirements of the regulatory agency
- These results also support the safety profile of ArtemiC™ in humans, demonstrated in the interim analysis of the first 10 patients in the Phase IIa study (refer ASX release 20 August 2020)
- These results demonstrated the targeted outcome - reporting no adverse impact on the major organs at dosing levels of 48ug, 96ug and 196ug per kg rat
- Histology testing included pathological examination of the organs: liver, heart, brain, spleen, spinal cord, sciatic nerve, kidney (L+R), lungs and tongue
- Testing was completed on a total of twenty-four rats at the Science in Action Laboratory in Ness Ziona, Israel (4 groups – 3 study drug dosages and control)
- ArtemiC™ is designed with the scientific aim to target inflammatory complications due to dysregulation of the immune response ("cytokine storm"), such as arises in the context of COVID-19, and is currently being evaluated in a Phase IIa clinical trial on COVID-19 infected patients in Israel
- ArtemiC™ is formulated with the patented nano delivery MyCell™ technology, a unique platform to deliver natural ingredients more effectively in higher concentrations to the cells, improving bioavailability of natural ingredients

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 the results of a pre-clinical *in vivo* safety and toxicity study, including histology testing, of ArtemiC™ on rats which achieved the targeted study outcome, reporting no pathological changes or differences between the study groups. These results are significant and positive as they provide critical additional information on the toxicological evaluation of ArtemiC™ regarding its effect on the organs that were studied and augment the base data supporting the current Phase IIa clinical trial on COVID-19 patients and future clinical studies

ArtemiC™ *In Vivo* safety and toxicity results on rats

Following the safety and toxicity testing completed on mice (refer ASX release 27 July 2020) and in line with FDA requirements for product registration requiring two types of rodents in pre-clinical trials, MGC Pharma completed an *in vivo* safety and toxicity pre-clinical study, including histology testing, on twenty-four rats. This included 4 groups with three 3 study drug dosages being 48ug, 96ug and 196ug per kg rat and a control group. The rats were observed and tested for clinical changes over seven days. This study included pathological examination of the organs: liver, heart, brain, spleen, spinal cord, sciatic nerve, kidney (L+R), lungs and tongue.

The results concluded there were no pathological changes in all tested animal samples, which is a promising outcome for the Company and its ongoing clinical trial and studies on ArtemiC™.

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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. The 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.

These positive results demonstrating no pathological impact on the major organs of the animals in the study is significant as this completes the FDA requirements for toxicology tests for new drug development. The results show the safety and tolerability of ArtemiC™ in two rodent studies under the very strict requirements of the regulatory agency. The FDA provide recommendations around General Nonclinical Considerations, which include the requirement for toxicity testing. The FDA also provide a guidance document for toxicity studies[1].

ArtemiC™ is specifically targeted to treat COVID-19, which may cause organ damage and lung complications, so it is essential that pertinent data is collected. This pre-clinical data on rats will support future efficacy clinical studies in Phase IIb and Phase III in COVID-19 patients. The Phase IIb study will include efficacy endpoints and dose finding elements, based on these current animal study results.

Roby Zomer, Co-founder and Managing Director of MGC Pharma, commented: "The histology results provide the Company with important insights into the potential effects of ArtemiC™ on major organs. Pleasingly, no adverse impacts were recorded on major organs which provides critical information in relation to planning for future clinical studies".

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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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[1] Source: FDA Guidance Document

ANNEXURE A

The ArtemiC™ animal study was performed in the Science in Action Laboratory in Ness Ziona, Israel, under Ethics Committee Approval Number IL-20-8-351.

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. 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 an animal model. 24 rats, 8 weeks old, body weight M 240-270 gr F 180-210gr were used for the experiment. Rats were randomised and into groups and in each group 6 rats were treated in splash route of administration into the oral cavity on day 1 with the experimental substances according to the group table. Each animal was weighed prior to treatment.

Study groups -
Group 1 (n=3M + n=3F): 50ul saline per rat
Group 2 (n=3M + n=3F): 48ug ArtemiC™/ per Kg rat
Group 3 (n=3M + n=3F): 96ug ArtemiC™/ per Kg rat
Group 4 (n=3M + n=3F): 192ug ArtemiC™/ per Kg rat

During all 7 days of the experiment the animals were monitored for observation and weight to detect the appearance of abnormal clinical signs.

No clinical signs were observed in the animals.

After 7 days blood from all rats was taken for a full panel of hematology and chemistry. Blood 0.2 for an unbound EDTA test for hematology panel, and 0.5 ml for a separable gel test tube, to 0.25 ml serum for a panel of blood chemistry composition

After blood collection the animals were sacrificed and the organs: brain, lungs, heart, liver, spleen and kidneys were removed, weighted and kept in formalin 4%, and sent for pathological examination.

Histology

Organ/Tissue Collection and Fixation

Liver, heart, brain, spleen, spinal cord (cervical, thoracal and lumbar), sciatic nerve, kidney (L+R), lungs and tongue, of 24 rats, were harvested, fixed in 4% Formaldehyde arrived to Patho-Logica in the fixative and kept in the fixative for 48 hours, for further fixation. Then, the tissues were trimmed, put in embedding cassettes and processed routinely for paraffin embedding. Seven cassettes were prepared per animal.

Slide Preparation

Paraffin blocks were cut at approximately 4 microns thickness. The sections were put on glass slides and stained with Hematoxylin & Eosin (H&E).
The slides were subjected to histological evaluation by Dr. Loeb.

Light Microscopy Photography

Pictures were taken using Olympus microscope (BX60, serial NO. 7D04032) at objective magnification of X4 and X10 and microscope's Camera (Olympus DP73, serial NO. OH05504).

Histological evaluation

The H&E stained slides were examined, described and scored by the study Pathologist, using a semi-quantitative grading of five grades (0-4), for the severity of the pathological changes (Schafer et al.):
Grade 0 – The tissue appears normal, without any changes at all.
Grade 1 – Minimal pathological findings.
Grade 2 – Mild pathological findings.
Grade 3 – Moderate pathological findings.
Grade 4 – Severe pathological findings.

Results

- All samples looked normal and didn't show any pathological changes.
- The pathological evaluation, including grading, in individual animals in the different groups is given below in the table A.

Table A. A semi-quantitative analysis of the histological findings, using a scoring scale (see previous page)										
Group/ treatment	**Animal NO.**	**Brain**	**Heart**	**Lungs**	**Liver**	**Kidneys**	**Spleen**	**Spinal cord**	**Sciatic nerve**	**Tongue**
Group 1 (G1)	11	0	0	0	0	0	0	0	0	0
	12	0	0	0	0	0	0	0	0	0
	13	0	0	0	0	0	0	0	0	0
	14	0	0	0	0	0	0	0	0	0
	15	0	0	0	0	0	0	0	0	0
	16	0	0	0	0	0	0	0	0	0
G1	**Mean**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
N=6	**SD**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Group 2 (G2)	21	0	0	0	0	0	0	0	0	0
	22	0	0	0	0	0	0	0	0	0
	23	0	0	0	0	0	0	0	0	0
	24	0	0	0	0	0	0	0	0	0
	25	0	0	0	0	0	0	0	0	0
	26	0	0	0	0	0	0	0	0	0
G2	**Mean**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
N=6	**SD**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Group 3 (G3)	31	0	0	0	0	0	0	0	0	0
	32	0	0	0	0	0	0	0	0	0
	33	0	0	0	0	0	0	0	0	0
	34	0	0	0	0	0	0	0	0	0
	35	0	0	0	0	0	0	0	0	0
	36	0	0	0	0	0	0	0	0	0
G3	**Mean**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
N=6	**SD**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Group 4 (G4)	41	0	0	0	0	0	0	0	0	0
	42	0	0	0	0	0	0	0	0	0
	43	0	0	0	0	0	0	0	0	0
	44	0	0	0	0	0	0	0	0	0
	45	0	0	0	0	0	0	0	0	0
	46	0	0	0	0	0	0	0	0	0
G4	**Mean**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
N=6	**SD**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**