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LSE Code: MXC

Further findings on ArtemiC™ Rescue as anti-inflammatory agent for COVID-19 and post COVID-19 syndrome

Key Highlights:

- ArtemiC™ Rescue (**ArtemiC™**) designed with the scientific aim to target viral infections with inflammatory complications, and was successfully evaluated on COVID-19 infected patients in a double-blind, placebo-controlled Phase II clinical trial.
- Preclinical and Clinical results to date have demonstrated ArtemiC™'s mechanism of action as an anti-inflammatory and immunomodulatory agent effective in the prevention of increased cytokine production, found in different variants and mutations of COVID-19; the forerunner of cytokine storm – believed to be the main reason for mortality in severe COVID-19 patients.
- Preclinical trial work, completed by MGC Pharma, showed the ability of ArtemiC™ to decrease the markers of inflammation (IFN-g, IL-1a and TNF-a), in the bronchoalveolar lavage fluid (BALF) of mice in the animal model of cytokine storm related to COVID-19 and in human trials to control the inflammation process in COVID-19 patients.
- Successful ArtemiC™ Phase II clinical trials performed in India and Israel have demonstrated the capacity of ArtemiC™ to improve and expedite the clinical recovery in mild to moderate patients suffering from COVID-19.

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 announce further results from the Phase II clinical and preclinical studies on ArtemiC™, evaluating the efficacy on anti-inflammatory agents for increased cytokine, which is found in different variants and mutations of COVID-19 and post COVID-19 syndrome.

The mechanism of action of ArtemiC™ is focused on the anti-inflammatory effect and prevention of cytokine storm – believed to be the main reason for mortality in COVID-19 patients. Preclinical and clinical results to date support ArtemiC™ being effective for addressing cytokine over production in all tested COVID patients. On 15 December 2020, the Company released to the ASX results from its Phase II clinical trial results from patients in India and Israel.

The preclinical trial "Evaluation the Efficacy of ArtemiC™ Treatment in ARDS Model in Mice" was performed in the SIA preclinical Lab (GLP certified) in Israel.

The ARDC model is the recommended preclinical animal model for the cytokine storm for the prediction of the human model of COVID-19 patients. The level of the pro-inflammatory markers was measured in blood and BALF (bronchoalveolar lavage fluid) of the mice going through the cytokine storm. The results demonstrated decreased blood and BALF cytokine levels in the study arm treated by ArtemiC™. Refer to Annexure A for additional information on the preclinical study and summary of results.

These findings support the understanding of the mechanism of action of ArtemiC™ and additional potential application of the study product. This data will be used in the design of future clinical trials of the Company in different indications.

Following the successful Phase II clinical trial results (refer ASX release 15 December 2020), ArtemiC™ demonstrated efficacy in COVID-19 infected patients. Patients in the treatment group fully clinically recovered within 15 days of follow up. The ArtemiC™ results delivered a full safety and efficacy profile, demonstrating its ability to improve and expedite the clinical recovery in mild and moderate COVID-19 patients.

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MGC Pharma continues the preclinical development on ArtemiC™ while progressing with the clinical development program for CimetrA™ as an Investigational Medicinal Product (IMP) to demonstrate the full efficacy and pharmacokinetic profile of the treatment in a Phase III clinical trial (submitted on the clinical drug development program of IMP version of ArtemiC™).

Importantly once the inflammation process associated with COVID-19 is under control, the effects of ‘long COVID’, the post COVID syndrome should be minimised. MGC Pharma will initiate a sub-trial in combination with the upcoming Phase III clinical trial to prove this hypothesis.

As per the FDA recommendations and based on the last findings, MGC Pharma will initiate a sub-trial for patients who complete the Phase III trial, observing them for an additional three (3) months to document the post COVID syndrome symptoms both in the treatment and placebo groups.

Roby Zomer, Co-founder and Managing Director of MGC Pharma, commented: “The findings from the phase II clinical trials which are supported by the completed preclinical trial results, continue to demonstrate the effectiveness of ArtemiC™ in treating patients with different variants of COVID-19.

“We are now looking to get ArtemiC™ into more territories as a supplement and herbal health product following these findings.”

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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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Annexure A

Preclinical Study details

Animals: mice
 Gender: male
 Sample size: 55
 Age: 8 weeks old

Study groups:

Time in hours	Route of administration	mcl	Dosage (mcg)	Treatment	Number	Group
0	0	0	0	Naive	5	1
0	0	0	0	LPS	10	2
1-	Spray Once	8	48	LPS+Artemic	10	3
1-	Spray Once	16	96	LPS+Artemic	10	4
1-	Spray Once	8	48	Artemic	10	5
1-	Spray Once	16	96	Artemic	10	6

Route of administration: Oral spray.

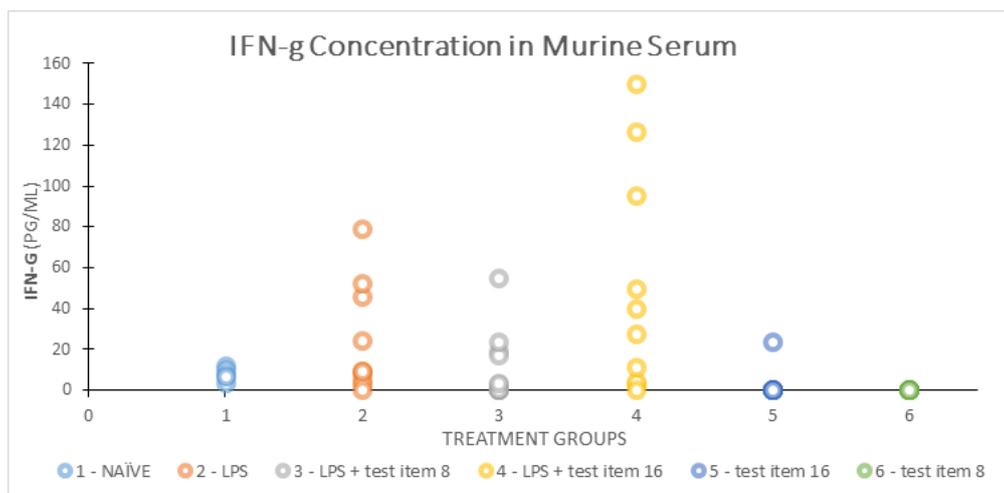
Treatment: Once by Oral spray 1h before LPS administration as indicated in the study groups table.

For a dose of 48 micrograms / mouse, 8 microliters of stock solution Add to 24 microliters saline and spray with micropipette into the oral cavity.

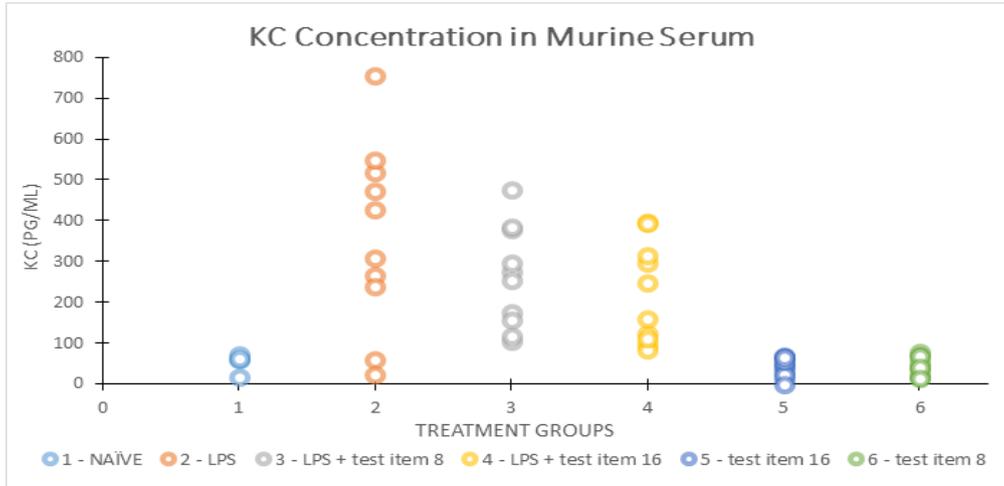
For a dose of 96 micrograms / mouse, 16 microliters of stock solution were added to 24 microliters of saline and spray with micropipette into the oral cavity.

Statistical analysis was performed using Excel software. P-value was calculated using Student’s T-test (2-tailed distribution, unequal variance). For statistical analysis “undetected” samples were considered as 0.

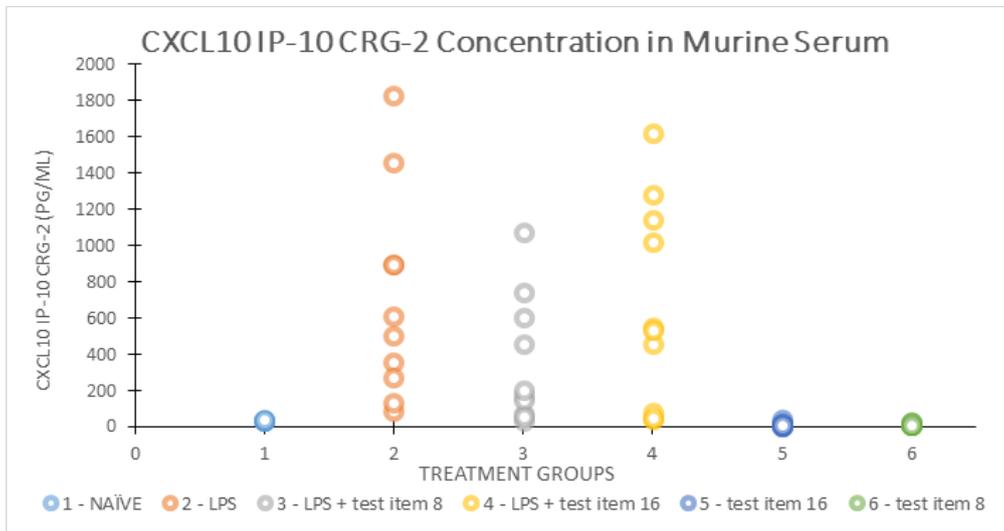
The summary of the results is presented below:



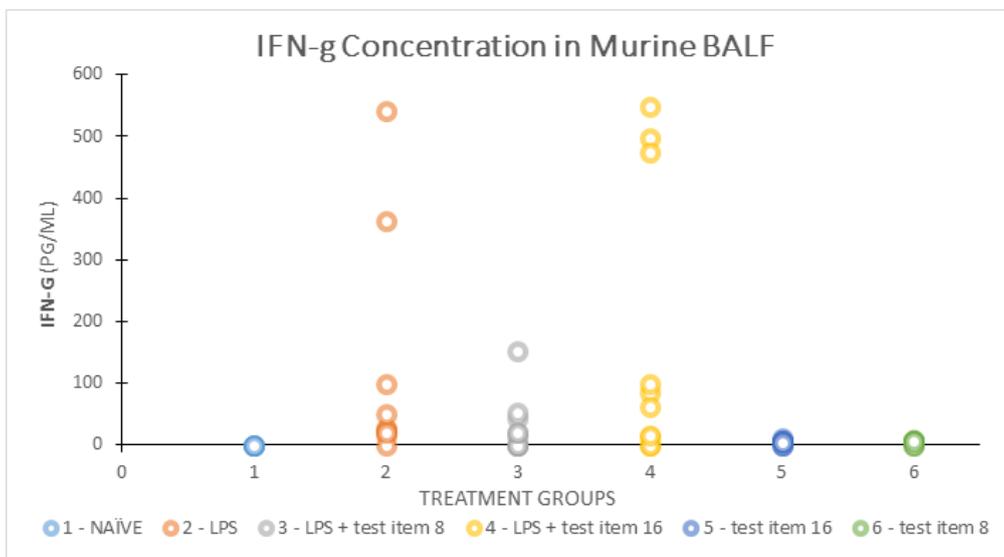
IFN-g in serum of mice



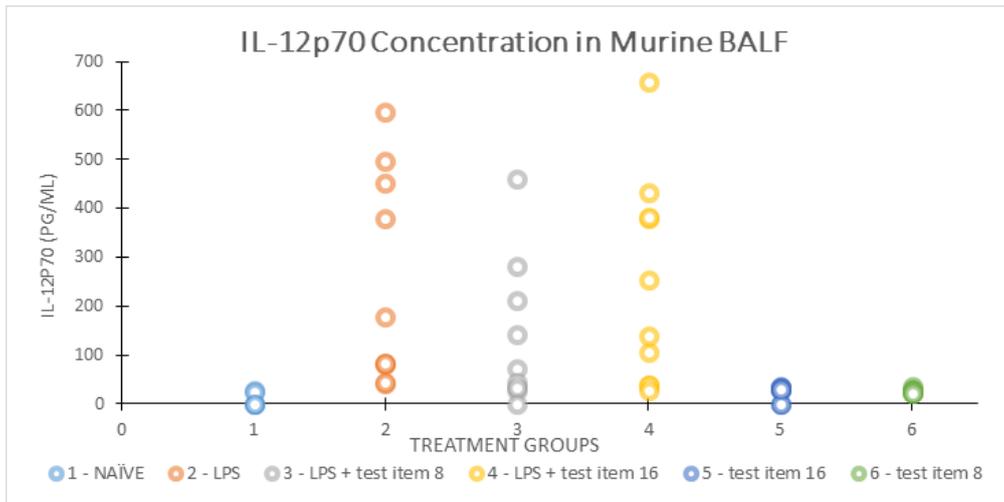
KC (Neutrophil chemokines) in serum of mice



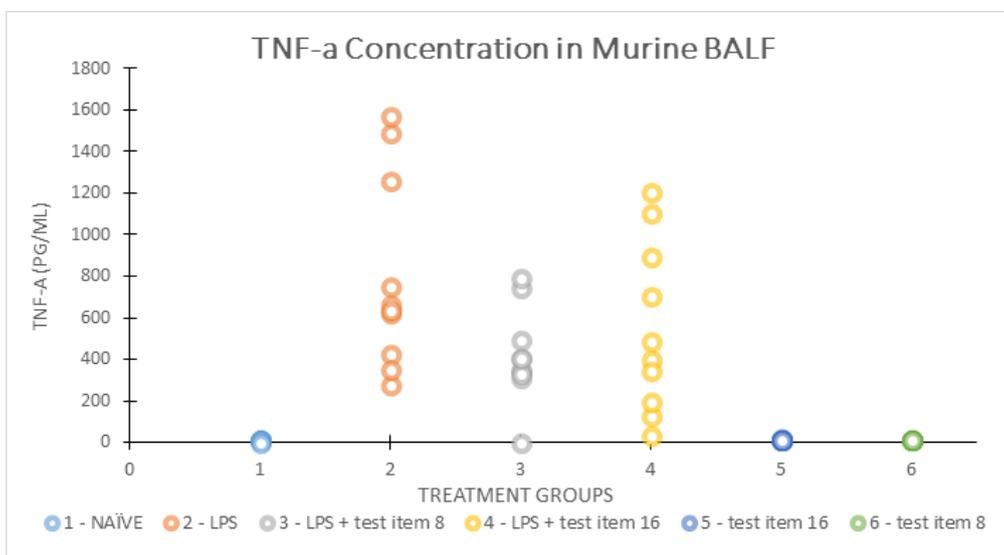
CXCL10 IP-10 CRG-2 in serum of mice



IFN-g in BALF



IL-12p70 in BALF



TNF-a in BALF

These results support ArtemiC™ mechanism of action hypothesis. Decreased cytokines in blood and bronchoalveolar lavage fluid of induced cytokine storm animal model explain the ability of ArtemiC™ to prevent cytokine storm in multiple etiology inflammatory condition, including (but not limited) pulmonary tract infection. Chemokines, decreased in both fluids (blood and BALF) support the process by the mediating of the immune response. This multi chain reaction, caused by chemokines and cytokines on the cellular and protein levels explain and support the results of the Phase II clinical study in ArtemiC™.