MGC Pharmaceuticals Limited

Last Friday, MGC and AMC Holdings Inc. ('AMC') senior executives met with University of South Florida ('USF') department heads to plan the commencement of a US Clinical Trial for CimetrA™, further to the US Supply and Distribution Agreement the parties executed in August 2021. Scheduled to begin in Q3 2022 following the Group's submission of an application to the FDA as a materially advanced Investigational New Drug ('IND'), they also advanced discussions regarding regulatory approvals for the use of MGC's leading phyto-cannabinoid medicines, CogniCann® and CannEpil®, in the USA under existing early patient access schemes. A further announcement released on Monday also detailed results from a preclinical *in vitro* study that indicates CimetrA™ has a wide-ranging application as an anti-inflammatory treatment, potentially making it suitable for use in a number of additional common health conditions. Taken together, these announcements represent important steps forward for MGC, not only in terms of building on the clinical research that has already been carried out in Israel and India to create the foundations required for CimetrA™ to secure FDA regulatory approval, but also that it prospectively widens access for all the Group's phyto-medicine products to the world's largest healthcare market.

MGC deepens its relationship with AMC

AMC is a recently incorporated SPV with expertise in healthcare and vast experience within US governmental bodies. It sees botanical and natural medicines as an area of significant growth potential in the US and MGC as an international leader in the sector. It is led by CEO, Brett Scott, who spent 20 years working within the US government including the Department of Justice and US Senate.

The original binding US Market Access and Distribution Agreement that was signed on 26 August 2021, was for a minimum MGC products order of US$24 million over 3 years including CannEpil®, CogniCann® and CimetrA™. Within this, AMC remained responsible for managing US-based clinical trials for MGC's phytomedicines and for seeking US regulatory approvals including from the FDA, for products that they intend to distribute in the US. As such, executives from both firms are currently working with the USF's Botanical Medicine Research and Education Consortium to conduct the first US-based clinical trial of CimetrA™. This is scheduled to begin in Q3 2022, following the Group's submission of an application to the FDA as a materially advanced IND.

CimetrA™'s Phase II double-blind clinical trial in 2020 demonstrated the efficacy of the treatment for patients suffering from moderate COVID-19, with none of the patients in the treatment group requiring additional oxygen, mechanical ventilation, or admission to intensive care, in comparison with 23.4% of the placebo group requiring further assistance. Its mechanism appears effective in treating the cytokine storm, which is seen as a sudden increase in different pro-inflammatory cytokines associated with COVID-19, and was able to treat both mild and severe cases of the disease.

The follow-on Phase III study has been designed to evaluate efficacy and safety when treating hospitalised patients diagnosed with COVID-19, and to provide additional data for claims on the product. Following receipt of ethics committee approval on 23 March 2021 the trial, which has Israeli Ministry of Health approval, proposed to enrol a total of 252 patients to be conducted over a 28-day period at the two clinical sites, Rambam Health Care Campus and Nazareth Hospital EMMS, in Israel. Interim results of the trial were expected to be released in August 2021, but this was delayed due to the enrolling of

Stock Data

Share Price:	0.91p
Market Cap.:	£24.82m
Shares in issue:	2,728m
52 week high/low:	3.95p/0.85p

Company Profile

Sector:	Healthcare
Ticker:	MXC
Exchange:	LSE, ASX

Activities

MGC Pharmaceuticals Limited ('MGC', 'MGC Pharma' 'the Group') is a European-based, vertically integrated bio-pharma company supplying EU-GMP phytomedicine and phytocannabinoid-derived products to patients.

www.mgcpharma.com.au/

Share Price Performance since Admission*

**MGC Phamraceuticals shares Admitted to the Standard Listing Segment of the Official List on 9 February 2021 Sourrce: LSE*

Past performance is not an indication of future performance.

Turner Pope contact details

Tel: 0203 657 0050
Email: info@turnerpope.com
Web: www.turnerpope.com

Andrew Thacker
Corporate Broking & Sales

Barry Gibb
Research Analyst

TPI acts as sole UK broker to MGC Pharmaceuticals Limited.

Attention is drawn to the disclaimers and risk warnings at the end of this document.

Retail clients (as defined by the rules of the FCA) must not rely on this document.

patients into a Phase IIb Dosing Study for CimetrA™ which aimed to determine its optimum patient dosage which would then be utilised in the Phase III trial.

Once enrolments into the Phase III trial recommences, the Group intends to expand this trial to strategic global jurisdictions. Existing trials and observations suggest that a number of specific features distinguish CimetrA™ from other currently available treatments, which potentially widens its international commercial opportunity.

These include:

- Ease of use: CimetrA™ can be self-administered as an oral spray. CimetrA™ is a natural medicine comprised of Boswellia and Curcumin.
- Efficacy of the delivery mechanism: the treatment is delivered to the oral mucosal cells, where it is most efficiently absorbed into the body in a highly concentrated form, without first being degraded by amino acids in the stomach or absorbed through the stomach lining.
- CimetrA™ is "variant agnostic": it helps the body respond to the virus infection; it is not an anti-viral, which often has more efficacy against one variant than another.
- Graft Polymer's (LSE: GPL) GraftBio™ self-nanoemulsifying drug delivery system ('SNEDDS') increases the bioavailability of the active ingredients delivered to cells.
- Many patients cannot or will not take existing medications owing to contraindications or the fact that they are not considered "high risk" enough to receive the treatment. CimetrA™ is targeting to fill that gap in the USA for healthcare providers and public health officials looking for a treatment between antivirals and infusion therapy versus "go home and let us know if you get worse."
- Cost: CimetrA™ is selling overseas for a fraction of the cost of monoclonals and half the cost of antivirals, according to a report published by the Institute for Clinical and Economic Review ('ICER')

CimetrA™ - Preclinical trial indicates potential for wider-ranging application as an anti-inflammatory

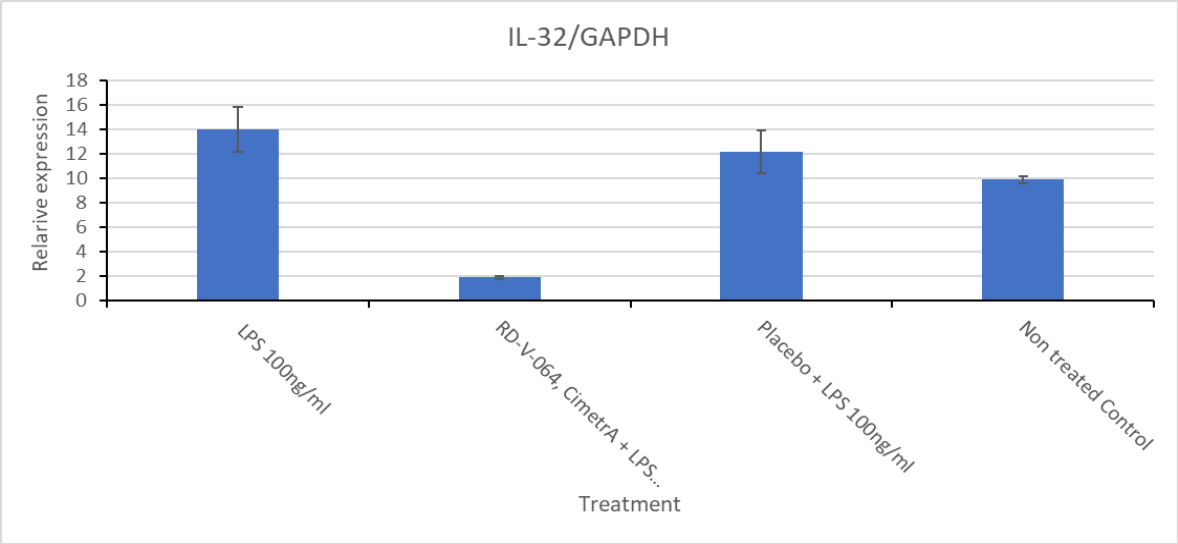
Results from a preclinical *in vitro* study indicate that CimetrA™ has a wide-ranging application as an anti-inflammatory treatment, through the modulation of the production of pro-inflammatory cytokines based on their gene expression and transcription factors. This suggests potential uses of the drug for the treatment of conditions including Rheumatoid Arthritis, Inflammatory Bowel Disease, Asthma, Psoriasis and Chronic Obstructive Pulmonary Disease.

The study was undertaken by an Israeli contract research organisation, Science in Action, which examined the mechanism of the drug's anti-inflammatory effect in human peripheral blood mononuclear cells ('PBMC'). These round nucleus cells consist of lymphocytes (T cells, B cells, NK cells) and monocytes, whereas erythrocytes and platelets have no nuclei, and granulocytes (neutrophils, basophils, and eosinophils) have multi-lobed nuclei.

This supports previous findings from a study undertaken by MGC in 2020 on patients suffering from moderate COVID-19, where CimetrA™ was shown to modulate the body's overproduction of cytokines, which can lead to a Cytokine Storm, seen as a sudden increase in different pro-inflammatory cytokines, including IL-1, IL-6 and TNF-α. This method of action appears to be achieved through inhibition on mRNA expression and complete abortion of transcription factors that induce such secretion. One of the key findings is its ability to effectively block the IL-32mRNA expression, which is the pro-inflammatory cytokine related to the conditions noted above.

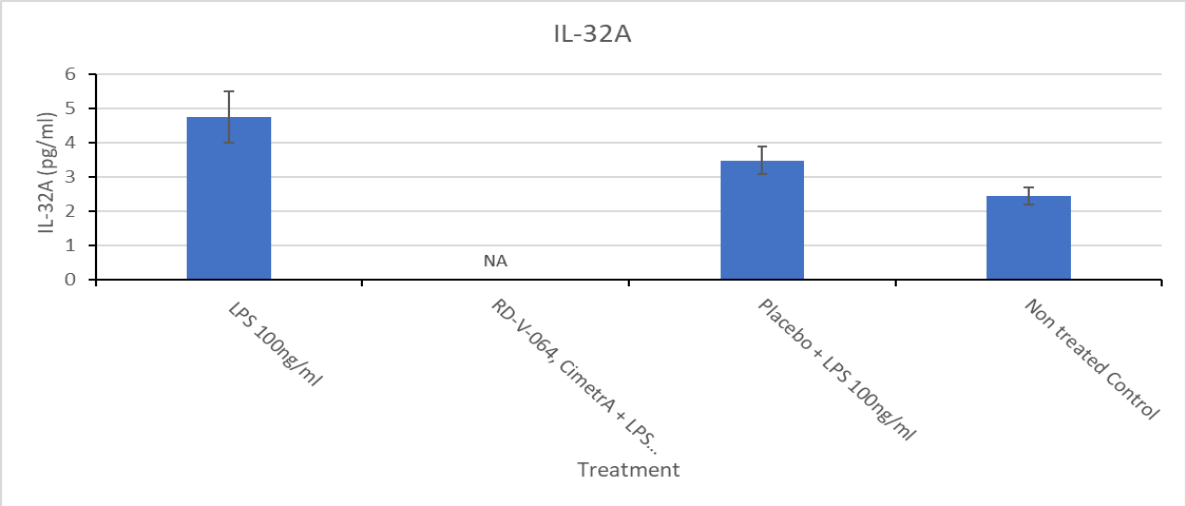
MGC's Board is now making plans for the next phase of CimetrA™'s clinical journey and further announcements are anticipated in due course.

The first figure (overleaf) demonstrates IL-32 being able to stimulate the secretion of inflammatory cytokines by activating NF-κB and p38 mitogen-activated protein kinase:



Source: MGC, RNS of 27 June 2022

The second figure (below) demonstrate CimetrA™ completely aborted LPS-induced IL-32 secretion in PBMCs.



Source: MGC, RNS of 27 June 2022

MGC positioned to fulfil its growth ambitions

The past year has seen MGC pass a number of major milestones. During a busy period, it laid the foundations for the Group's continued growth and future success, which included securing entry into the world's largest healthcare market, while also producing its strongest consecutive quarter-on-quarter result in Q3 2021 from sales receipts, allowing it to deliver over AUD$2.2m of cash inflows. Adding the net proceeds from the £5.5m (gross) capital raising completed on 30 November 2021 which, together with existing cash-in-hand, left it with AUD$4.0m at end-March 2022. Together with undrawn facilities, this appears to adequately resource the Group to service expected CimetrA™ needs through to its anticipated Emergency Use Authorisation in different jurisdictions, with high-margin scale production through its Maltese facility coming onstream this coming summer as it also continues to co-sponsor clinical studies for its expanded ArtemiC™ product range. In tandem with this, MGC is expected to further progress CimetrA™'s Phase III clinical trial alongside Phase IIb trials of phytocannabinoid derived CannEpil® (targeting c.50 million people globally who suffer with Epilepsy and specifically the 33% of those with Drug Resistant Epilepsy), and design of the next phase of CogniCann®'s clinical trials which will define appropriate End Points and patient sample size.

Accordingly, the remainder of 2022 looks set to remain a busy and exciting period for the MGC, as it continued to add value to its portfolio of pharmaceutical products on route to their gaining regulatory approval and/or securing international commercial partnerships/distribution agreements with larger sector players.

THIS DOCUMENT IS NOT FOR PUBLICATION, DISTRIBUTION OR TRANSMISSION INTO THE UNITED STATES OF AMERICA, JAPAN, CANADA OR AUSTRALIA.

Conflicts

This is a non-independent marketing communication under the rules of the Financial Conduct Authority ("FCA"). The analyst who has prepared this report is aware that Turner Pope Investments (TPI) Limited ("TPI") has a relationship with the company covered in this report. Accordingly, the report has not been prepared in accordance with legal requirements designed to promote the independence of investment research and is not subject to any prohibition on dealing by TPI or its clients ahead of the dissemination of investment research.

TPI manages its conflicts in accordance with its conflict management policy. For example, TPI may provide services (including corporate finance advice) where the flow of information is restricted by a Chinese wall. Accordingly, information may be available to TPI that is not reflected in this document. TPI may have acted upon or used research recommendations before they have been published.

Risk Warnings

Retail clients (as defined by the rules of the FCA) must not rely on this document.

Any opinions expressed in this document are those of TPI's research analyst. Any forecast or valuation given in this document is the theoretical result of a study of a range of possible outcomes and is not a forecast of a likely outcome or share price.

The value of securities, particularly those of smaller companies, can fall as well as rise and may be subject to large and sudden swings. In addition, the level of marketability of smaller company securities may result in significant trading spreads and sometimes may lead to difficulties in opening and/or closing positions. Past performance is not necessarily a guide to future performance and forecasts are not a reliable indicator of future results.

AIM is a market designed primarily for emerging or smaller companies and the rules of this market are less demanding than those of the Official List of the UK Listing Authority; consequently, AIM investments may not be suitable for some investors. Liquidity may be lower and hence some investments may be harder to realise.

Specific disclaimers

TPI acts as sole UK broker to MGC Pharma Limited ('MGC Pharma). MGC Pharma is dual-listed on the London Stock Exchange's Standard List and the Australian Stock Exchange's ASX. TPI's private and institutional clients may hold, subscribe for or buy or sell MGC Pharma's securities.

Opinions and estimates in this document are entirely those of TPI as part of its internal research activity. TPI has no authority whatsoever to make any representation or warranty on behalf of MGC Pharma.

General disclaimers

This document, which presents the views of TPI's research analyst, cannot be regarded as "investment research" in accordance with the FCA definition. The contents are based upon sources of information believed to be reliable but no warranty or representation, express or implied, is given as to their accuracy or completeness. Any opinion reflects TPI's judgement at the date of publication and neither TPI nor any of its directors or employees accepts any responsibility in respect of the information or recommendations contained herein which, moreover, are subject to change without notice. Any forecast or valuation given in this document is the theoretical result of a study of a range of possible outcomes and is not a forecast of a likely outcome or share price. TPI does not undertake to provide updates to any opinions or views expressed in this document. TPI accepts no liability whatsoever (in negligence or otherwise) for any loss howsoever arising from any use of this document or its contents or otherwise arising in connection with this document (except in respect of wilful default and to the extent that any such liability cannot be excluded by applicable law).

The information in this document is published solely for information purposes and is not to be construed as a solicitation or an offer to buy or sell any securities or related financial instruments. The material contained in the document is general information intended for recipients who understand the risks associated with equity investment in smaller companies. It does not constitute a personal recommendation as defined by the FCA or take into account the particular investment objectives, financial situation or needs of individual investors nor provide any indication as to whether an investment, a course of action or the associated risks are suitable for the recipient.

This document is approved and issued by TPI for publication only to UK persons who are authorised persons under the Financial Services and Markets Act 2000 and to professional clients, as defined by Directive 2004/39/EC as set out in the rules of the Financial Conduct Authority. This document may not be published, distributed or transmitted to persons in the United States of America, Japan, Canada or Australia. This document may not be copied or reproduced or re-distributed to any other person or organisation, in whole or in part, without TPI's prior written consent.