MGC Pharmaceuticals Limited

MGC yesterday received Ethics Committee approval for the Phase III Clinical Trial ('the Trial') of CimetrA™ on Patients Diagnosed with COVID-19 (SARS-CoV-2). CimetrA™ is designed with the scientific aim to target viral infections with inflammatory complications, having already been successfully evaluated on infected patients in a double-blind placebo controlled, Phase II clinical trial. Although a significant initial worldwide supply agreement has already been signed for ArtemiC™ Rescue in its form of a food supplement, the product has now also undertaken a name change to CimetrA™, in recognition of the transfer of its status to an Investigational Medicinal Product ('IMP') ahead of the Trial's commencement. Importantly in this respect, CimetrA™ encapsulates Graft Polymer Limited's GraftBio™ SNEDDS technology (Self-Nano Emulsifying Drug Delivery System), as a unique platform to deliver higher concentrations of the natural active ingredients more effectively in to the cells, thereby improving their bioavailability.

Ethics Committee approvals

MGC has received Ethics Committee approvals from Rambam Health Care Campus, Haifa and Nazareth Hospital EMMS in Israel, for the randomised, placebo-controlled Phase III clinical trial be undertaken on patients diagnosed with COVID-19. This will evaluate the efficacy and safety of CimetrA™ in the treatment of a large group of moderate hospitalised patients diagnosed with COVID-19 as well as providing additional information for claims on the product as an IMP, including essential data to plan for the future regulatory pathway for its registration as a prescription drug.

MGC already has the required facilities, permits and approvals to start production of CimetrA™ as an IMP. The Trial itself is expected to commence in the coming week before concluding in September 2021, with results available in October 2021. Accordingly, the Group is presently seeking similar regulatory approvals from additional clinical sites in Israel and Brazil. Based on three natural ingredients, consisting of Curcumin, Boswellia serrata, plus Artemisinin capsulated in GraftBio™ SNEDDS delivery system to improve the bioavailability of the active ingredients, MGC is planning to develop further preclinical and clinical programs for other indications, considering that CimetrA™'s anti-inflammatory effect might be effective in a wide spectrum of inflammatory and autoimmune diseases, like IBD, RA, flu, pneumonia etc.

Phase III Clinical Trial

The Trial's primary endpoint is given as the time to sustained clinical improvement, defined as a National Early Warning Score 2 (NEWS2) of </= maintained for 24 Hours in comparison to routine treatment (measured on days 7, 14, 28). Secondary endpoints, amongst other things, include the number of participants with dependence on oxygen supplementation through day 28 since onset of symptoms and change in inflammatory marker levels compared to baseline.

The NEWS2 is based on a simple aggregate scoring system in which a score is allocated to physiological measurements, when patients present to, or are being monitored in hospital. Six simple physiological parameters form the basis of the scoring system: respiration rate, oxygen saturation, systolic blood pressure, pulse rate, level of consciousness or 'new confusion' and temperature. The patient may, for example, display new-onset confusion, disorientation and/or agitation, where previously their mental state was 'normal'. This is a pragmatic approach, with key emphasis on system-wide standardisation and the use of physiological parameters that are already routinely measured in hospitals and in pre-hospital care.

Stock Data

Share Price:	4.00p
Market Cap.:	£90.7m
Shares in issue:	2,267m
UK high/low since Admission:	8.95p/2.38p

Company Profile

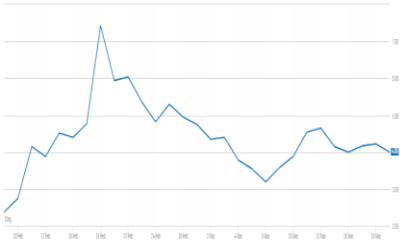
Sector:	Healthcare
Ticker:	MXC
Exchange:	LSE, ASX

Activities

MGC Pharmaceuticals Limited ('MGC', 'MGC Pharma' 'the Group') is a European-based, vertically integrated bio-pharma company supplying EU-GMP 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
andy.thacker@turnerpope.com

Zoe Alexander
Corporate Broking & Sales
zoe.alexander@turnerpope.com

Barry Gibb
Research Analyst
Tel: 0203 657 0050
barry.gibb@turnerpope.com

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At this time, practitioners estimated that about one-fifth of all infected patients see their condition progress to involve the lower respiratory tract and onward to Acute Respiratory Distress Syndrome ('ARDS'), resulting in the development of severe symptoms. The virus invades and enters the type 2 alveolar epithelial cells via the host receptor ACE-2 and starts to undergo replication to produce more viral Nucleocapsids. The virus-laden pneumocytes then release many different cytokines and inflammatory markers such as interleukins (IL-1, IL-6, IL-8, IL-120 and IL-12), tumour necrosis factor-α (TNF-α), IFN-λ and IFN-β, CXCL-10, monocyte chemoattractant protein-1 (MCP-1) and macrophage inflammatory protein-1α (MIP-1α). This 'cytokine storm' acts as a chemoattractant for neutrophils, CD4 helper T cells and CD8 cytotoxic T cells, which then begin to get sequestered in the lung tissue. These cells are responsible for fighting off the virus but, in doing so, are responsible for the subsequent inflammation and lung injury. The host cell undergoes apoptosis with the release of new viral particles, which then infect the adjacent type 2 alveolar epithelial cells in the same manner. Due to the persistent injury caused by the sequestered inflammatory cells and viral replication leading to loss of both type 1 and type 2 pneumocytes, there is diffuse alveolar damage eventually culminating in an acute respiratory distress syndrome.

Protocols for the Trial were finalised by the MGC Pharma Clinical Advisory Team and successfully provided to the Ethics Committee for their approval. As has been noted previously, due to the Trial being defined as a 'Special Clinical Trial', there is no requirement for any additional approval from the Israeli Ministry of Health for commencement. With placement of the clinical trial insurance now complete, the work expected to commence within a week. Adopted methodology following screening visit, includes the study drug being administrated twice a day, morning and evening during (day 1 and day 2), with patients randomised in 1:1 ratio to compare the study drug in addition to Standard of Care or to Placebo in addition to Standard of Care. Being evaluated on a total target number of 252 infected patients across clinical sites in Israel and Brazil, the Trial will be conducted over a period of 28 days for each patient and is expected to conclude during September 2021, with results available during October 2021.

The Trail is designed to test CimetrA™ on moderate hospitalised patients with the novel coronavirus for the purpose of treating the pathophysiological repercussions of infection. Although much has been discovered regarding the transmission and presentation, less is known about the pathophysiology of COVID-19. It will therefore assess the efficacy and safety of the product's natural anti-inflammatory formulation with the supporting ingredient Artemisinin as Antiseptic peroxide bridge, bringing together well-known natural active ingredients with immunomodulatory properties, possessing antiviral, antioxidant and anti-inflammatory activities relevant to multiple aspects of the pathophysiology associated with COVID- 19 (Cheng-wei 2001, Dhivya and Rajalakshmi 2017).

Importantly, they have been already tested in humans and found to have an amenable safety profile (Chainani-Wu 2003, Medhi, Patyar et al. 2009, Storka, Vcelar et al. 2015). Their profile is further supported by data from *in vitro* and *in vivo* laboratory studies that demonstrated the potential of curcumin to be of benefit in the management of viral respiratory distress syndrome (Leitman 2012, Avasarala, Zhang et al. 2013, Guzel, Kanter et al. 2013, Ghandadi and Sahebkar 2017, Lelli, Sahebkar et al. 2017). Having identified an emergency need for fast tracked clinical studies to address the medical challenges presented by COVID-19, MGC's plan proposes to test the hypothesis that a micellar formulation of the well-studied active ingredients artemisinin and curcumin may be clinically beneficial in the management of the disease.

MGC is now well funded to fulfil its growth ambitions

As Roby Zomer, co-founder and Managing Director of MGC noted at the time of the Group's Admission to trading on London's Standard Listing Segment on 9 February 2021, the £6.5m (gross) new funding raised through a strongly supported equity placing along with existing cash resources "will primarily be used to support the Company's growth ambitions as we continue to expand our manufacturing capabilities, increase our product range and expand into new and existing key markets." As was detailed in a MGC's Prospectus published on 3 February 2021, the new funds will be applied to:

- Meet costs associated with the Phase III clinical trial of CimetrA™ planned for H1 2021;
- Meet the costs associated with a Phase IIb clinical trial of CannEpil®;
- Increase distribution of the Group's product range and expansion into new key markets to drive sales growth and future revenue, including Brazil and major EU countries; and
- Meet the registration costs for CimetrA™/ArtemiC™ in new markets, including Russia, the Middle East and Europe; and for general working capital purposes, including completing construction of the Group's proposed manufacturing facilities in Malta.

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