MGC Pharmaceuticals Limited

MGC has confirmed its recently completed Phase II Clinical Trial ('the Study') for its proprietary dementia treatment, CogniCann®, demonstrates full safety and preliminary efficacy profile. The Study also reinforced confidence in the phytocannabinoid-derived Investigational Medicinal Product's ability to inhibit deterioration in the behaviour of patients with Dementia, of which Alzheimer's Disease is the most common cause. As such, the positive results will now be used in the design of the next phase of its clinical trials, including defining appropriate End Points and patient sample size. Recognising the problems caused by existing cholinesterase inhibitor treatments that presently dominate the therapeutic space for treatment of such conditions, which include a wide range of sometimes disabling side effects along with a reported disproportionate prevalence of fatal outcomes, means that the medical world continues to seek alternatives to address this rapidly growing market, which had an estimated value of US$3.76 billion in 2021. Understanding that phytomedicines tend to be significantly free of such toxicities, major players like Allergan, Eisai Co. Ltd., Novartis AG, Pfizer Inc., etc. that operate in this competitive area may consider potential for partnering with MGC as its development of CogniCann® progresses in the coming years.

CogniCann® - Delivers positive Phase II Clinical Trial Results

Having demonstrated its ability to cross the blood-brain barrier, CogniCann® is designed to treat patients with Dementia and Alzheimer's disease. The oral spray's specific ratio of delta-9-tetrahydrocannabinol (THC) to cannabidiol (CBD) in its composition is assessed for improvement in behaviour and cognition in dementia patients.

The Study assessed the drug's safety profile by monitoring adverse events and a range of observational tests undertaken by a research nurse who met with each participant to discuss their adverse event records, while also measuring their heart rate and blood pressure twice a week. The participant's weight and body composition measures, such as lean body mass, bone mass and fat mass were similarly measured utilising non-invasive methods. In assessing both the safety profile and the efficacy of CogniCann® against a placebo, the Study results identified no difference against placebo groups, thereby indicating that it is safe to use by patients with dementia.

The efficacy of CogniCann® was assessed using three established and standardised criteria, with measured outcomes as follows:

1. The participant's NPI-NH Score using the Neuropsychiatric Inventory Nursing Home Version ('NPI-NH') Questionnaire, which is based on responses from the participants, and from caregivers involved in their daily care. Results of the study showed that after 44 days, patients in the Placebo group experienced a deterioration in their condition, based on their NPI-NH score, compared with the stable neuropsychiatric profile of those patients treated with CogniCann®, indicating that the early-stage use of the drug may be beneficial in the treatment of dementia patients. See NPI-NH score chart overleaf.
2. Aggressive behaviour is one of the most serious of the disturbances experienced by dementia patients, and is a common cause for psychiatric referral, admission to hospital and drug treatment. During the 44-day study period the treatment groups Cohen-Mansfield Agitation Inventory Aggressive subscale improved by 24%, compared with the Placebo Group which improved by 4%. See improvement compared to the placebo in chart overleaf.
3. The Cohen-Mansfield Agitation Inventory ('CMAI') is a 29-item scale widely

Stock Data

Share Price:	1.18p
Market Cap.:	£32.19m
Shares in issue:	2,728m
UK high/low since Admission:	3.95/1.02p

Company Profile

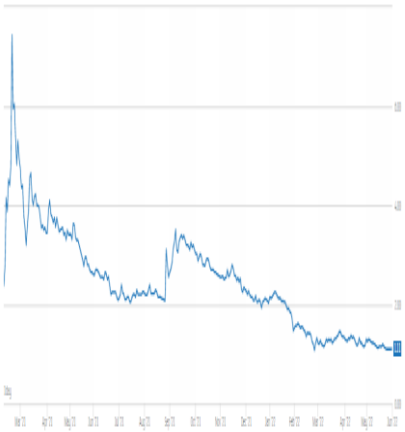
Sector:	Healthcare
Ticker:	MXC
Exchange:	LSE, ASX

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.

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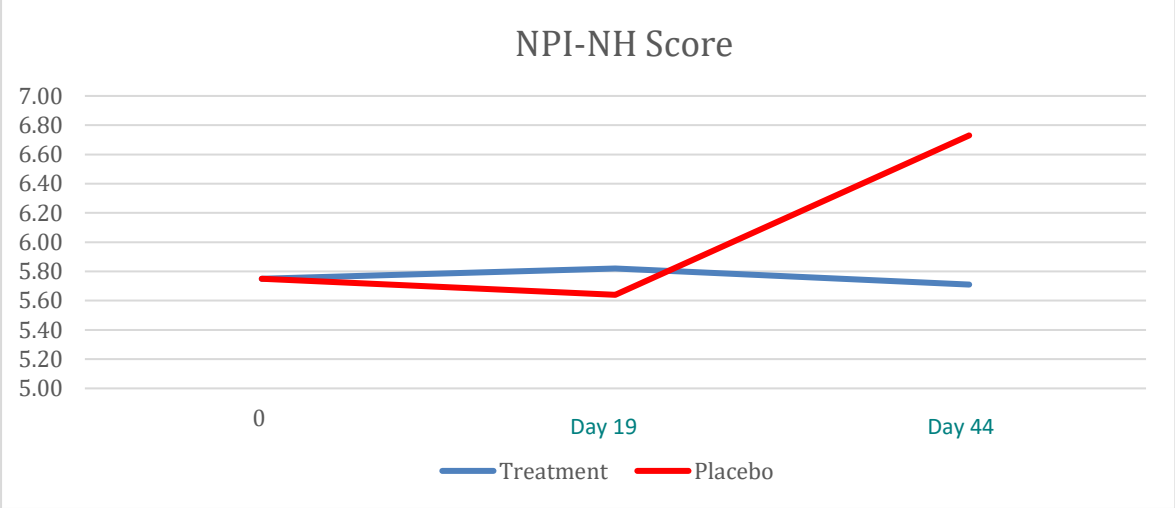
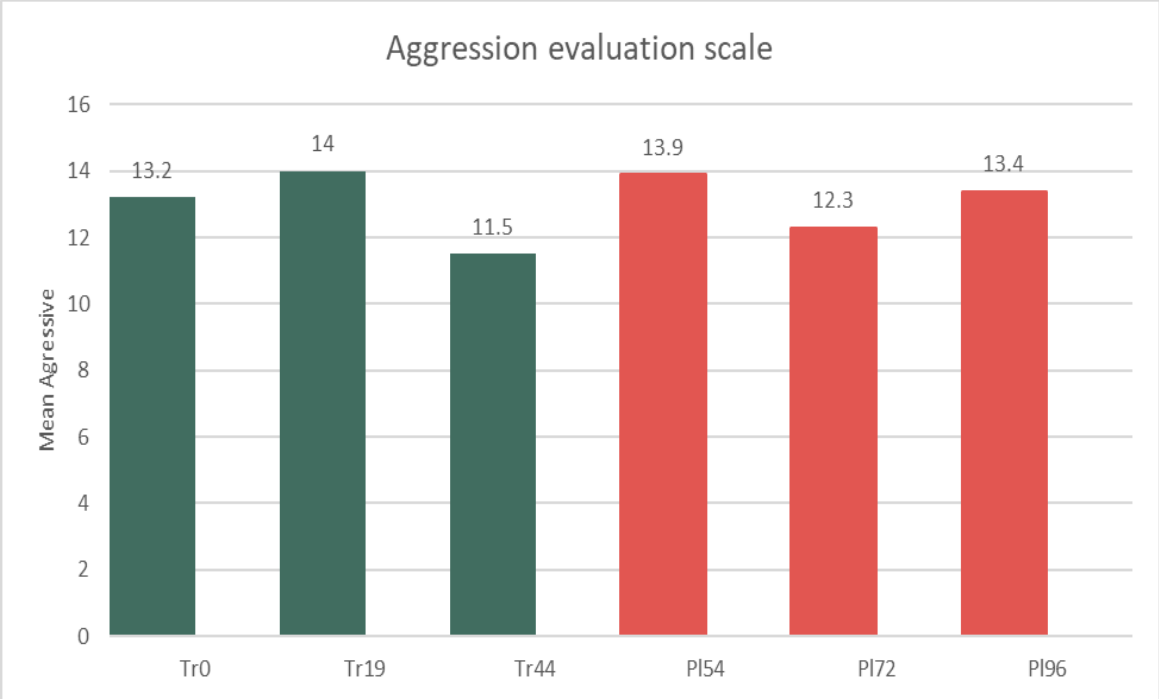
used to assess the frequency of manifestations of agitated behaviours in elderly persons, which is completed by a proxy (i.e., family carer or nursing home staff members). The Study demonstrated that the Treatment Group's CMAI score improved by c.17%, from 69 to 57, compared with the Placebo Group's improvement of c.8% over the 44-day period.

Graph Showing the NPI-NH Score of Patients Administered CogniCann® Versus Placebo



Source: MGC, RNS of 6 June 2022

Graph Demonstrating Change in Aggressive Behaviour between the Treatment and Placebo Groups



Note: Green Columns – Treatment Group, Red Columns – Placebo or Control Group

Source: MGC, RNS of 6 June 2022

Note that the Clinical Trial, which commenced in March 2020, initially planned to enrol 50 patients from a number of Aged Care Facilities across Perth, Western Australia. As a result of the COVID-19 pandemic and the resulting restrictions place on accessing Aged Care Facilities by Australian government agencies, however, the time taken to complete the trial was longer than anticipated, resulting in the number of patients enrolled in the trial being reduced from 50 to 22.

The double-blind cross-over Clinical Trial was undertaken in conjunction with the University of Notre Dame in Western Australia and involved eligible patients commencing a six-week treatment course with CogniCann®, before switching (crossing over) to a six-week course of placebo, with a two-week 'washout' period between the two arms.

Market Opportunity – International treatment for Alzheimer's Disease is expanding rapidly

The global Alzheimer's disease treatment market is expected to grow from US$4.71 billion in 2021 to US$5.08 billion in 2022, representing at a compound annual growth rate ('CAGR') of 7.9%. The market is expected to expand further to US$6.94 billion by 2026 based on a CAGR of 8.1%, according to the Global Alzheimer's Disease Treatment Market Report 2022 prepared by ResearchAndMarkets.com. Treatment is dominated by cholinesterase inhibitors (also known as acetylcholinesterase inhibitors), which are a class of drugs that prevent acetylcholine from being broken down normally in the body. Major players in the treatment market include Allergan, Eisai Co. Ltd., Novartis AG, Pfizer Inc., Merz Pharma, H. Lundbeck A/S Biogen, AstraZeneca and F. Hoffmann-La Roche Ltd. North America represented the largest territory by sales in 2021 and although the USA Alzheimer's Association projects all US States to face a rise of at least 14% in the number of affected people by 2025 due to the increase in the geriatric population, the Middle East is expected to be the fastest growing region over the forecast period. Being a global condition, however, it remains widely prevalent across multiple international regions, including Asia-Pacific, Western Europe, Eastern Europe, North America, South America, Middle East and Africa.

In October 2019, MGC commissioned a Market Projections Study for CogniCann® by Alacrita Research, to assess the drug's potential market size. This review estimated that in Europe and the UK alone, there were approximately 1.5 million suffers of mild to moderate sufferers of Alzheimer's Disease.

Datamonitor Survey Extrapolating Values taken from 223 Physicians Countrywide in 2015

Territory	AD population	% diagnosed mild	% mild receiving drug treatment	% diagnosed moderate	% moderate receiving drug treatment	Total mild-AD	Total mild and moderate-AD
UK	776,950	44%	67%	40%	81%	229,045	480,777
France	386,546	43%	77%	39%	85%	127,986	256,126
Spain	275,553	35%	90%	46%	94%	86,800	205,950
Germany	537,512	37%	76%	40%	82%	151,149	327,453
Italy	317,043	37%	82%	40%	87%	96,191	206,522
Average		*39%*	*78%*	*41%*	*86%*		
Total	2,293,604					**691,171**	**1,476,828**

Data taken from Datamonitor who surveyed 223 physicians in 2015 and extrapolated values countrywide – Accessed May 2019

Source: MGC, RNS of 6 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 in the world through a US$24m 3-year Supply and Distribution Agreement with USA based AMC Holdings, 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 year 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.

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