Human Research Ethics Committee Approval for Australian Controlled Trial on the effect of CannEpil™ on Driver Competency and Performance

MGC Pharmaceuticals Ltd (ASX: MXC, 'MGC Pharma' or 'the Company'), a European based 'Seed to Pharmacy' bio-pharma company focused on developing and commercialising cannabinoid derived medicines, is pleased to announce that it has received Human Research Ethics Committee (**HREC**) approval to conduct a controlled trial to assess the effect of CannEpil™ on driving performance, while additionally providing safety data required for the European Medicines Agency (**EMA**) and the Therapeutic Goods Administration (**TGA**) product registration. CannEpil™ is a high CBD, low THC formula (20:1) developed for the treatment of drug resistant epilepsy, and is the Company's proprietary pharmaceutical grade cannabinoid derived medicine authorised for prescription as an Investigational Medicinal Product (**IMP**) both in Australia and the United Kingdom.

Key Highlights:

- HREC approval received to conduct a controlled trial on the effect of CannEpil™, MGC Pharma's proprietary pharmaceutical product targeting the treatment of refractory epilepsy, on driving performance (**the Trial**)

- CannEpil™ is a 20:1 cannabidiol (CBD) to tetrahydrocannabinol (THC) compound formula developed and manufactured at the Company's European GMP manufacturing facility

- This will be one of the first trials globally to assess the impact of cannabis based medical products and driving competency with the intention of providing sufficient evidence to impact legislation in favour of permitting patients taking CannEpil™ and other similar products to drive

- In addition to assessing impact on driving performance, the Trial will collect safety data required for product registration by the EMA and TGA

- Approval enables commencement of the Trial which is being conducted in collaboration with the Swinburne University of Technology, Melbourne (**the University**) and Cannvalate Pty Ltd, one of Australia's leading medical cannabis companies

- The Trial will compare the driving performance of healthy patients treated with CannEpil™ with the driving performance of a placebo group, while collecting safety data

- Under current legislation Australian states forbid patients taking cannabis based medical products from driving, which has been shown to reduce patient uptake

Roby Zomer, Co-founder and Managing Director of MGC Pharma, commented: "We are hoping this trial will clearly demonstrate that it is safe to drive while on CannEpil™, while collecting safety data required for registration by the EMA and TGA. It has been documented that a key reason for individuals in Australia to decline cannabis products for medical purposes that may benefit them is that it would inhibit them from driving. We are delighted to be working in collaboration with the Swinburne University of Technology and Cannvalate to conduct this industry leading, and much needed, research."

Sud Agarwal, CEO of Cannvalate, commented: "The Cannvalate research team is delighted to be conducting this trial in collaboration with MGC Pharmaceuticals and the University to investigate if consuming CannEpil has any adverse effect on driving performance. It's the first Australian study to quantify how THC-containing cannabinoid medications will affect your driving. This could have significant impact on many adult epileptics who currently are unable to drive while taking cannabinoid medication."

Further Information

Human Research Ethics Committee (**HREC**) has granted the Swinburne University of Technology (**the University**) and Cannvalate in collaboration with MGC Pharmaceuticals, with the necessary approval to commence a clinical trial that will assess the impact of CannEpil™ on driving performance, while gathering safety data integral for registration with the EMA and TGA.

CannEpil™ is a high CBD, low THC formula (20:1) developed for the treatment of drug resistant epilepsy, and is the Company's proprietary pharmaceutical grade cannabinoid derived medicine authorised for prescription as an Investigational Medicinal Product (**IMP**) both in Australia and the United Kingdom.

It has been understood that this inability to drive while under treatment has prevented individuals pursing treatment that they would otherwise benefit from. To address this MGC Pharma, in collaboration with the University and Cannvalate, has designed the controlled trial to demonstrate that CannEpil™ does not negatively impact driving performance with the objective of supplying sufficient supporting data for a future request for legislation change.

The Trial shall involve 30 healthy individuals (15 men and 15 women) aged 21-60 years; half of which shall be administered CannEpil™ and the remaining half to be given a placebo. The driving performance of the two groups shall be tested by attending two experimental sessions using a high-fidelity driving simulator at the University over a 14 day period. In particular the Trial will assess whether CannEpil™ causes changes in the standard deviation of the lateral position (SDLP) variable obtained from the driving simulator compared to placebo.

Following this approval from the HREC, participant recruitment is expected to commence Q4CY2019 once all import/export permits are granted which is currently being obtained by the Company. Once participant recruitment has commenced the Trial will proceed with data collection, data analysis and data reporting with the Company expecting the final report within 9 months of commencement.

The EMA and TGA have strict requirements on data and controlled trials in order to achieve product registration, including observing any adverse effects on healthy patients. While foremost this is a trial to assess the impact, if any, of CannEpil™ on driving performance, it allows the Company to continue collecting all data required for registration.

As patient uptake of CannEpil™ and other cannabis products for medical purposes increases, the issue of driving while being treated with these products has become increasingly prevalent. Under current legislation, patients using cannabis based products are not permitted to drive as roadside testing is unable to differentiate between legal and illegal use, and there is not sufficient data for regulators to create a level of impairment, as has been done with alcohol.

--Ends--

For further information, please contact:

UK IR/Media Advisors	**MGC Pharmaceuticals Ltd**
Gaby Jenner/ Catherine Leftley	Brett Mitchell
St Brides Partners Ltd	Executive Chairman
+44 (0) 207 236 1177	+61 8 6382 3390
gaby@stbridespartners.co.uk	info@mgcpharma.com.au
catherine@stbridespartners.co.uk	

About MGC Pharma

MGC Pharmaceuticals Ltd (ASX: MXC, OTCQB: MGCLF) is an EU-based BioPharma company with many years of technical clinical and commercial experience in the medical cannabis industry. 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 cannabinoids-based pharmaceuticals products for the growing demand in the medical markets in Europe, North America and Australasia.

Follow us through our social media channels

About the Swinburne University of Technology

Swinburne University of Technology is a world-class university creating social and economic impact, through science, technology and innovation. Swinburne researchers have a reputation for high-quality research with strengths in astronomy, physics, engineering, materials science, computer science and information technology, design and innovation, health sciences, neurosciences, and mental health. The Swinburne research institutes foster interdisciplinary collaboration and deeper research connections with industry, business and community to maximise Swinburne's impact. Our institutes provide leadership in data science, health and social innovation, smart cites and the future of manufacturing. Underpinned by leading digital technology platforms, our researchers are collaborating with industry through embedded partnerships to drive innovation and create impact.