

25 August 2020
ASX Code: MXC

Term sheet signed to establish joint venture for registration of ArtemiC as medicine in Russia, and oncology medicines

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Key Highlights:

- MGC Pharma has a binding term sheet in place with Dr. Svetlana Kopachevskaja, a leading Russian doctor and medical researcher to establish a joint venture company for medical products in the Russian market
- Joint venture company will commence the registration process for the anti-inflammatory product, ArtemiC as a medicine for the Russian market
- ArtemiC is designed with the scientific aim to target viral infections with inflammatory complications which is currently being evaluated in a Phase IIa clinical trial on novel coronavirus 2019 (SARS-CoV-2) infected patients
- Registration of ArtemiC in Russia is expected to be fast-tracked post successful completion of the current Phase IIa clinical trial – approximately 9 months to registration as a medicine
- Distribution and sales of ArtemiC to Russia and CIS countries to be managed by existing MXC partner, Israeli medical products distribution company KS Kim, part of the SK Pharma group
- The term sheet was signed following the recent release of the ArtemiC interim Phase IIa clinical trial results on COVID-19 patients, successfully meeting all Primary Endpoints (refer ASX release 20 August 2020)
- Importantly the new agreement also includes the registration of 15 MGC Pharma formulations and generic oncology medicines, leveraging off the Company's existing oncology expertise and IP led by Dr Jonathan Grunfeld
- The joint venture company will be owned 70% by MGC Pharma and 30% by the leading Russian doctors and investment partners involved

MGC Pharmaceuticals Ltd (ASX: MXC, 'MGC Pharma' or 'the Company'), a European based biopharma company specialising in the production and development of phytocannabinoid-derived medicines, is pleased to announce it has signed a term sheet to partner with Dr Svetlana Kopachevskaja, and key associated investment partners (the '**Partners**') to establish a joint venture company to facilitate registration of ArtemiC as a medicine in Russia, and register 15 MGC Pharma formulations and generic oncology medicines for the Russian market. The joint venture company will be 70% owned by MGC Pharma and 30% owned by the Partners.

Dr. Svetlana Kopachevskaja has years of knowledge in the production, development and registration of Oncological medications. Dr Kopachevskaja was formerly the Deputy Director of the Federal State Budgetary Institution (FSBI), National Medical Centre of Oncology of the Ministry of Health in Russia and Naukoprofi branch Director at the Blokhin National Medical Research Centre of Oncology of the Ministry of Health in Russia.

Dr Kopachevskaja has an outstanding reputation throughout the Russian medical community and has been responsible for implementing the procedures for registration of new and innovative medicines. Dr. Kopachevskaja brings with her a highly credentialed team in the oncology medicine field, they are regulatory and production experts, which will assist in the development of the MGC formulas for registration in Russia.

The joint venture company will be managed by Dr Kopachevskaja and her team with assistance from MGC Pharma’s Europe-based team. The joint venture company will initially focus on registering ArtemiC in Russia as a medicine with the distribution of ArtemiC managed by existing MGC Pharma distributor KS Kim, part of the SK Pharma group (refer ASX release 13 May 2020). Key terms of the joint venture term sheet are included on Annexure A.

Subject to successful completion of the current Phase IIa ArtemiC clinical trial (results expected October/November 2020), the Company will be eligible to proceed with the registration of ArtemiC as a medicine in Russia. Importantly, the Company expects the registration process to be fast-tracked via submission of the dossier to the agency, taking only between 9-12 months. This is significantly faster than most medicines, due to the current global COVID-19 pandemic, which is usually 5-8 years.

Russia represents a key market of strategic growth for MGC Pharma and ArtemiC as it has recorded over 960,000 cases of COVID-19 to date, the fourth highest country globally, and is still recording significantly high COVID-19 infection rates. On 24 August 2020 Russia reported over 4,700 new cases of COVID-19 in 24 hours¹.

Registration of MGC Pharma formulations and generic oncologic medicines for the Russian Market

Along with registration of ArtemiC, the joint venture will also commence registration of an additional fifteen (15) formulations, consisting of MGC Pharma formulations and generic oncologic medicines, in Moscow for the Russian market. This leverages off the Company’s existing expertise, knowhow and IP in the Oncological field combined with the expertise of Dr. Kopachevskaja as the former Deputy Director of the FSBI, National Medical Centre of Oncology of the Ministry of Health in Russia. MGC Pharma is looking to utilise Dr. Kopachevskaja and her team to take MGC Pharma to the next level as a bio-pharma company and also plan in the future to export these medicines to the EU market, expanding on the initial Russian market target.

Annual cost of oncology services in Russia during 2019 (paid by the government health insurance) was US\$2.6bn². The Russian pharmaceutical medicine market for 2019 was valued at US\$11bn³.

Roby Zomer, Co-founder and Managing Director of MGC Pharma, commented: “We are delighted to be working with Dr Kopachevskaja and our partners to establish the joint venture and target the Russian market. Russia is an extremely large market and is still reporting very high numbers of COVID-19 infections. Importantly, our time to market for ArtemiC in Russia can be reduced significantly via the fast-track process. The Company also looks forward to working with Dr. Kopachevskaja and her team for the development and registration of MGC Pharma formulations and generic oncologic medicines”.

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About MGC Pharma

MGC Pharmaceuticals Ltd (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.





¹ World Health Organization

² Oncological Service in Russia (Infrastructure and Budgets), 2020

³ Facts from IQVIA, EAEU & CIS, Russia, January-December 2019

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

The Binding Term Sheet to establish a Joint Venture ('JV') held 70% by MXC and 30% by the Partners

- The first phase of the JV will be to register ArtemiC and other oncological formulations for the Russian market and sublicense it to Russian manufacturer
- Following success of the first phase, the JV will examine establishing a GMP production facility equipped with equipment for the manufacturing of MGC formulas which include generic oncologic medicine
- MGC Pharma to fund the JV with a budget to be agreed and will manage all operational aspects of the JV
- The Partners will be responsible for the liaison with the governmental authorities and all regulatory procedures in Russia and the JV will administered by the Partners
- MGC Pharma has the right to conduct due diligence investigations of the project and the partners, should the results of the due diligence be unsatisfactory the Company has the right within 90 days to terminate the Term Sheet ('Condition Precedent').
- There is no term stipulated in the agreement however it is subject to the Condition Precedent, MGC Pharma and the Partners will aspire to enter into a binding definitive agreement based on the material terms of the Term Sheet within one hundred and twenty (120) days, which period can be extended at the mutual agreement of the parties. Upon execution, the Definitive Agreement shall terminate and replace the Term Sheet in its entirety. Without derogation from the foregoing, should the Condition Precedent be fulfilled within such period, but the parties fail to sign the Definitive Agreements, then the Term Sheet shall constitute the Definitive Agreement for all purposes.
- The financial significance of the agreement will be established upon registration of the medicines and once purchase orders received for the products.