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MGC Pharma receives TGA approval to market epilepsy drug in Australia

October 11, 2018 | News

CannEpil in the treatment of adult patients with drug-resistant epilepsy. The first batch of CannEpilTM is expected to be available for sale in Australia by December 2018



Australia's MGC Pharmaceuticals is pleased to announce the receipt of formal authorisation for the availability of its product CannEpil for supply in Australia through specialist prescribers under the Authorised Prescriber Scheme.

This is a major milestone which represents the Company's progress towards becoming a world-leading Bio-Pharma company, with more than 10 years' clinical experience and a leading Scientific Advisory Board in place. It also signals the immediate commencement of commercial-scale production of CannEpil at MXC's EU GMP certified facility in Slovenia, and the start of revenue generation from the Company's core pharma activity.

The formal TGA authorisation follows Human Research Ethics Committee endorsement from St Vincent's Hospital Melbourne for the use of CannEpil in the treatment of adult patients with drug-resistant epilepsy. The first batch of CannEpil is expected to be available for sale in Australia by December 2018, and will be distributed under the agreement with specialist Australian pharmaceutical distributor, HL Pharma.

MGC Pharmaceuticals is working with a number of Australian based specialist doctors and neurologists, who will operate under the Ethics Committee approval in place and have applied to the TGA for specific approval to prescribe CannEpil to their patients who suffer from drug resistant epilepsy.

Roby Zomer, Co-founder and Managing Director, MGC Pharmaceuticals commented “We are delighted to announce the availability of our first product CannEpil for supply under the Authorised Prescriber Scheme. This is a significant achievement for us and we are very excited at the prospect of ramping up production to a commercial scale and bringing CannEpil to Australia.” “This important step validates MXC’s seed-to-pharma strategy with the start of commercial revenues from our first Investigational Medicinal Product offering.”

Carol Ireland, Chief Executive Officer, Epilepsy Action Australia commented “This is a significant milestone for epilepsy patients and other patient communities. It is another important step in improving access to potentially life-changing medications, and part of a global trend to recognize the valid medical benefits of cannabis.” “As advocates of patient rights, we are pleased to see progress, and a sign that patient needs and wants are heard and respected. We believe that Australia has a chance to lead the way in this global shift and we are proud that the epilepsy community and Epilepsy Action have played a significant part in bringing this about.”