

CMS Medical to distribute EndoBarrier in Brazil

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Singapore: GI Dynamics has entered into an agreement with CMS Medical, headquartered in Goiânia, Brazil, to distribute its lead product, EndoBarrier, a breakthrough therapy for type 2 diabetes and obesity. Under the agreement, CMS will be the exclusive distributor of EndoBarrier therapy in Brazil, following regulatory approval of the product in that country.

This agreement follows the recent submission for registration with the Agência Nacional de Vigilância Sanitária (ANVISA) for approval to market EndoBarrier in Brazil. GI Dynamics is working closely with SciTech Produtos Medicos (SciTech), a sister company of CMS, to help manage the regulatory process.

Mr Mark C Twyman, chief commercial officer, GI Dynamics, said that, "We are very pleased to establish this partnership with SciTech and CMS, with the combined entity being recognized as a premier distributor and manufacturer of minimally-invasive medical products in Brazil. Their proven track record of bringing innovative healthcare solutions to physicians throughout Brazil, coupled with their knowledge and understanding of the Anvisa registration process will be invaluable as we work toward regulatory approval and commercialization in this market. If all goes well, we expect to launch EndoBarrier therapy in Brazil in early 2014."

"We are excited to be working with GI Dynamics and look forward to leading the commercialization of EndoBarrier therapy following Anvisa approval," said Melchiades da Cunha Neto, co-founder, SciTech. "Our mission is to work with and bring to market the most advanced healthcare technologies and treatments. EndoBarrier Therapy is a novel, non-surgical treatment for type 2 diabetes and obesity, and we look forward to making it broadly available to physicians and patients in Brazil who are struggling to manage these diseases."

Delivered endoscopically (through the mouth) during a brief, non-surgical procedure, the EndoBarrier device acts as a physical barrier between food and the intestinal wall. Once in place, it begins working immediately and has been shown to lower HbA1c (blood glucose) to healthy levels and achieve weight loss of approximately 20 percent within one year. EndoBarrier therapy is currently available in select countries in Europe, as well as Australia, Chile and most recently, Israel. In January, GI Dynamics announced it had initiated its pivotal clinical trial of EndoBarrier in the US, the Endo Trial, for the treatment of patients who have uncontrolled type 2 diabetes and are obese.