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# FDA approves clinical trial of EndoBarrier

24 April 2013 | News | By BioSpectrum Bureau

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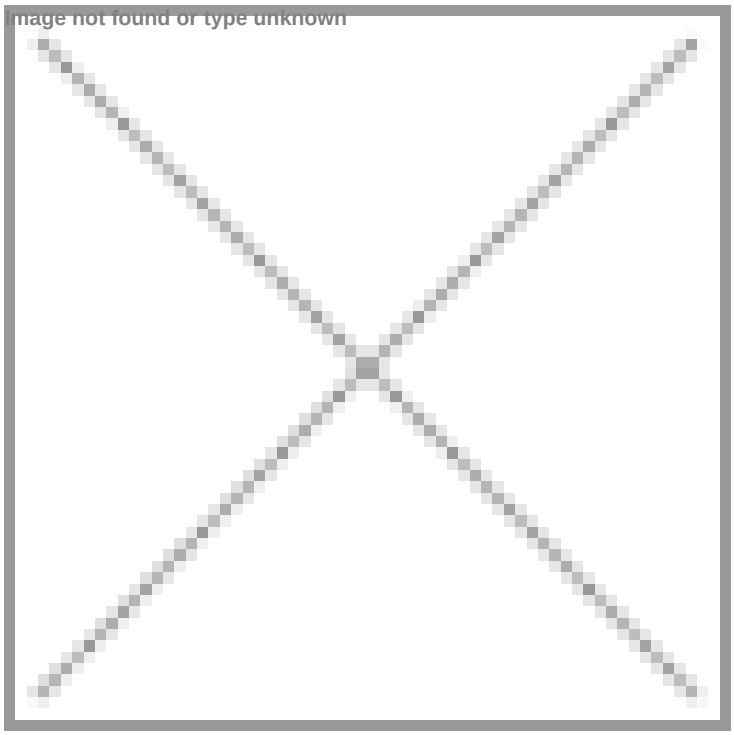


**Singapore:** GI Dynamics has received full approval from the U.S. Food and Drug Administration (FDA) to commence a 25-site pivotal clinical trial of EndoBarrier for the treatment of patients who have uncontrolled type 2 diabetes and are obese. Data garnered from the U.S. clinical study, named the ENDO Trial, will be used to support a Premarket Application (PMA) for EndoBarrier. This approval follows the Company's announcement in August that it had received conditional approval from the FDA.

EndoBarrier is a thin, flexible, tube-shaped liner that forms a physical barrier between food and a portion of the wall of the intestine. In 12 clinical studies conducted outside the United States and one conducted in the United States, with more than 500 patients, EndoBarrier has been shown to achieve rapid reductions in blood sugar levels, improvement of cardiovascular risk factors including blood pressure, cholesterol and triglycerides, and weight loss of approximately 20 percent in 12 months. EndoBarrier received CE Mark approval in 2010, and approval by the Therapeutic Goods Administration in Australia in 2011 for the treatment of type 2 diabetes and/or obesity for up to 12 months. EndoBarrier is currently commercially available in select countries in Europe, including Germany, Austria, the United Kingdom and the Netherlands, as well as Australia and Chile.

"Over the past several years, we have successfully completed extensive clinical studies and achieved several regulatory approvals outside the U.S., and it has been extremely rewarding to see the benefits EndoBarrier has brought to people living with type 2 diabetes," said Stuart A. Randle, president and chief executive officer, GI Dynamics. "We are very pleased to now

have full approval in the U.S. to commence a pivotal trial of this novel therapy. We look forward to providing updates on the progress of the ENDO trial and to submitting the results for PMA approval to sell EndoBarrier in the United States."