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GI Dynamics starts US trial of EndoBarrier

January 16, 2013 | News | By BioSpectrum Bureau



Singapore:Ã?Â GI Dynamics has initiated its US multicenter pivotal clinical trial of EndoBarrier, the Endo trial, for the treatment of patients, who have uncontrolled type 2 diabetes and are obese.

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 previous clinical studies, EndoBarrier has been shown to achieve rapid reductions in blood sugar levels and weight loss of approximately 20 percent in 12 months. EndoBarrier received CE Mark approval in 2010, and approval by the Therapeutic Goods Administration (TGA) in Australia in 2011 for the treatment of type 2 diabetes and/or obesity for up to 12 months.

"We're excited to initiate this important trial in the US," said Dr Lee M Kaplan, lead investigator and director of the obesity, metabolism and nutrition institute at the Massachusetts General Hospital and Harvard Medical School. "Results from the pilot studies of EndoBarrier have been very promising, and we look forward to determining the efficacy and safety of this device in this large, controlled, pivotal trial."

"The start of our US pivotal trial marks a major milestone on the road to bringing EndoBarrier to the millions of people in this country living with type 2 diabetes," said Mr Stuart A Randle, president and chief executive officer, GI Dynamics. "We appreciate the support of our investigators and clinical trial sites as we begin the process of enrolling patients and executing this landmark clinical trial."