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GI Dynamics gets FDA nod for diabetes and obesity trial

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Singapore: GI Dynamics received conditional approval from the US FDA to commence a pivotal clinical trial of the EndoBarrier for the treatment of patients who have uncontrolled type 2 diabetes and are obese. The EndoBarrier is already approved and commercially available in select markets, including Chile, Australia and several countries in Europe.

Mr Stuart A Randle, president and CEO, GI Dynamics, said that, "We are very pleased that the agency has chosen to recognize the substantial amount of scientifically sound data generated from our clinical trials conducted outside the US, allowing us to move directly into a pivotal trial. Going directly into a pivotal trial eliminates the need for a pilot trial and has the potential to accelerate commercialization of the EndoBarrier in the US."

The company can now move forward with the institutional review board (IRB) approval process that is required prior to enrolling patients into the pivotal study.

The pivotal trial is a randomized, multi-center, double-blind, sham controlled trial that is expected to enroll approximately 500 people living with uncontrolled diabetes and obesity, who meet the enrollment criteria. The trial is designed to assess improvements in diabetes over a treatment period of up to 12 months. The primary endpoint of the trial is improvement in HbA1c (a key blood sugar measure for diabetes) and secondary measures include weight loss and improvements in select cardiovascular risk factors, such as cholesterol.

GI Dynamics established an executive committee (EC) of leaders in metabolic disease and endoscopic techniques to oversee the clinical trial. The EC is led by committee chair Dr Lee Kaplan, Massachusetts General Hospital; Dr Louis Aronne, New York Presbyterian Hospital, Weill Cornell Medical Center; Dr John Buse, University of North Carolina at Chapel Hill; and Dr Steven Edmundowicz, Washington University in St. Louis.