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## **GI Dynamics Announces Data Demonstrating Immediate and Sustained Reduction in HbA1c in Patients with Type 2 Diabetes Using EndoBarrier™ Gastrointestinal Liner**

*Compelling Clinical Data Highlighted at First World Congress on Interventional Therapies for Type 2 Diabetes Show Improved Glycemic Control and Weight Reduction in Uncontrolled Diabetics*

NEW YORK--([BUSINESS WIRE](#))--GI Dynamics, a medical device company pioneering the development of new approaches to treat metabolic disorders, today announced new data regarding the EndoBarrier™, its novel, noninvasive device currently in clinical trials to treat obesity and type 2 diabetes. New data from a pilot clinical trial indicate that patients with uncontrolled type 2 diabetes using the EndoBarrier Gastrointestinal Liner achieved a statistically significant improvement of glycemic control in just one week as compared to a sham control. Most impressive was that the immediate improvement was independent of weight loss, suggesting a direct action on diabetes. This glycemic improvement was sustained throughout the duration of the study.

These findings were presented today by Lee M. Kaplan, M.D., Ph.D., associate professor of medicine at Harvard Medical School and director of the Weight Center at Massachusetts General Hospital, at the First World Congress on Interventional Therapies for Type 2 Diabetes in New York City.

“Obesity and type 2 diabetes have reached epidemic proportions, and the healthcare community is struggling to find new ways to improve the treatment of these devastating and often fatal diseases,” stated Dr. Kaplan. “The immediate and sustained reduction in HbA1c levels observed with EndoBarrier in this controlled clinical trial equal or exceed the glycemic control produced by leading pharmaceutical treatments. The rigorous trial design included a sham treatment group to compare with the device group – making these results even more compelling. We look forward to further data evaluating the potential role of the EndoBarrier as an option for treating patients living with type 2 diabetes.”

According to Christopher Sorli, M.D., F.A.C.E., Department of Endocrinology, Billings Clinic, Billings, Montana, lead clinical advisor in the EndoBarrier clinical trial and presenter at the World Congress, “It can take a patient up to two years on aggressive therapies to see the kind of drop in HbA1c that we are seeing in just 30 weeks with the EndoBarrier. The EndoBarrier provides a non-surgical, completely endoscopic technique for duodenal-jejunal bypass in patients with type 2 diabetes, and these preliminary results suggest durability of glycemic improvement throughout device implantation.”

HbA1c levels are a gold standard in the assessment of glycemic control and can provide an indication for how well diabetes is being managed. The HbA1c test measures the amount of glycosylated hemoglobin in the blood over a three month period. Glycosylated hemoglobin is a molecule in red blood cells that attaches to glucose (blood sugar). An individual will have more glycosylated hemoglobin if he or she has frequently elevated blood sugar levels.

### **Overview of Clinical Trial and Interim Results**

The clinical trial was designed to examine the EndoBarrier for the treatment of type 2 diabetes. In a single-blind, long term study, 18 patients with type 2 diabetes were prospectively randomized to receive either the EndoBarrier Gastrointestinal Liner (n=12) or a sham endoscopy (n=6). The primary endpoint was reduction of HbA1c (average blood glucose level over three months). Secondary endpoints included absolute weight loss, reduction in fasting glucose from baseline, improvement in post-prandial glycemic response, and reduction or discontinuation of oral hypoglycemic medications. The trial is now complete, and data are available on patients with the device for up to eleven months.

<http://www.businesswire.com/portal/s...>

The data show that EndoBarrier patients experienced a mean reduction of 2.9% ( $p=0.04$ ) of HbA1c glucose levels from baseline (8.9%) versus a mean 0.76% ( $p=0.04$ ) reduction from baseline (9.0%) for the sham arm for an average of 31 weeks (ranged from 16 to 44 weeks). These results support the initial findings announced at the American Diabetes Association annual meeting in June that the EndoBarrier rapidly improves glycemic control in type 2 diabetics at one week, independent of weight loss. As a point of reference, Dr. Kaplan noted the promising results observed in this small study with the EndoBarrier compare favorably to previously reported findings with the latest blockbuster diabetes treatment, Byetta<sup>®</sup>. According to published data, patients on Byetta reported a 0.8% reduction in HbA1c from baseline (8.6%) at 30-weeks (Diabetes Care 2005; 28; 1083-1091). Additionally, EndoBarrier patients experienced an average 27.5 lb. weight loss in this trial by week 30.

Most device patients experienced a substantial 51.6 point reduction of fasting blood glucose levels by one week, another key indicator of diabetic status. There was a 76.6 point reduction in fasting blood glucose levels at 20 weeks. Some device patients were able to stop taking their diabetes medication as blood sugar levels normalized. Patients in the sham-treatment group who did not receive the device experienced a 17.4 point reduction in fasting blood glucose levels at week one and 38.2 point reduction at 20 weeks. There was an immediate impact on glucose levels. EndoBarrier patients exhibited an 18.6% decrease in the area under the glucose curve during a meal tolerance test at week one versus an increase of 10.1% in the sham-treatment group.

"We have treated more than 100 patients with the EndoBarrier to date and are very pleased with the emerging safety and efficacy profile for this device. These data, combined with new engineering aspects of the device, will allow us to expand our clinical development activities of the EndoBarrier," stated Stuart A. Randle, chief executive officer of GI Dynamics. "Based on our success in this clinical trial, we anticipate launching larger, longer-term studies with an enhanced device design in 2009."

In 2007, the Centers for Disease Control and Prevention (CDC) estimated that 23.5 million adults in the U.S. have diabetes. Among these adults, type 2 diabetes accounts for about 90-95% of all diagnosed cases of diabetes<sup>1</sup>. Additionally, it is estimated that as many as 90% of individuals with type 2 diabetes are reported to be overweight or obese<sup>2</sup>.

### **About the EndoBarrier™ Gastrointestinal Liner**

GI Dynamics has developed the EndoBarrier Gastrointestinal Liner, a non-invasive, removable device, which is currently being tested in clinical trials around the world as a potential treatment option for obesity and type 2 diabetes. The EndoBarrier creates a physical barrier between ingested food and the intestinal wall, thereby changing the metabolic pathway by controlling how food moves through the digestive system. This mechanical bypass of the small intestine mimics the effects of gastric bypass surgery on a patient's metabolism, resulting in profound weight loss and remission of type 2 diabetes. The EndoBarrier can be easily implanted and removed endoscopically (via the mouth), without the need for surgical intervention.

### **About GI Dynamics**

GI Dynamics, a clinical-stage medical device company, is pioneering the development of new, noninvasive approaches to treat obesity, type 2 diabetes and related metabolic diseases. The Company's patented EndoBarrier™ technology is designed to deliver immediate metabolic control by modifying metabolic pathways. GI Dynamics has developed the EndoBarrier™ Gastrointestinal Liner, an orally delivered, removable device that lines a portion of the small intestine, resulting in weight loss and improved glycemic control. Early clinical data have shown that EndoBarrier provides weight loss and immediate resolution of type 2 diabetes. Additional clinical trials are ongoing to further evaluate the long-term clinical benefit of EndoBarrier in obese people and patients with type 2 diabetes. Based in Lexington, Massachusetts and founded in 2003, GI Dynamics is backed by top-tier investors including Advanced Technology Ventures, Catalyst Health Ventures, Cutlass Capital, Domain Associates, Johnson & Johnson Development Corporation, and Polaris Venture Partners. For more information, visit GI Dynamics online at [www.gidynamics.com](http://www.gidynamics.com).

<sup>1</sup> Centers for Disease Control and Prevention (CDC)

<sup>2</sup> American Obesity Association web site ([www.obesity.org](http://www.obesity.org))

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