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GI Dynamics Announces Promising Multi-Center Safety and Efficacy Data of EndoBarrier™ Gastrointestinal Liner for Pre-Surgical Weight Loss

New Clinical Data Presented at IFSO Show Excellent Short Term Weight Loss Results in Morbidly Obese Patients

BUENOS AIRES, Argentina--(BUSINESS WIRE)--GI Dynamics, a medical device company pioneering the development of new approaches to treat obesity and 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 multi-center, randomized clinical trial indicate that the EndoBarrier is a safe, noninvasive device with excellent short-term weight loss results in morbidly obese patients. These data showed that patients treated with the EndoBarrier lost on average, triple the weight of their diet control group. Specifically, at just 12 weeks, the device group lost 13.7 kg (30.2 lbs) versus 4.4kg (9.7 lbs) for the control group.

Also notable was that the device had a beneficial effect on type 2 diabetes, resulting in lower blood glucose levels and/or a reduction in diabetic medication for patients. These findings were presented today by Ruben Schouten, M.D., Maastricht University Medical Center, Netherlands, at the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) 13th World Congress in Buenos Aires, Argentina.

"These excellent short-term weight loss results and the reduction in blood glucose levels in just three months with the EndoBarrier - a non-surgical device - are extremely encouraging," stated Jan Willem Greve, M.D., Ph.D., professor of surgery, Maastricht University Medical Center, Netherlands, and co-principle investigator in the study. "The data underscore the role of the EndoBarrier as a potential new treatment option for people living with this chronic metabolic disease."

Overview of Clinical Trial Results

The clinical trial was designed to examine the safety and efficacy of the EndoBarrier in morbidly obese patients. In a multi-center, randomized clinical trial, 37 patients were treated—26 received the EndoBarrier Gastrointestinal Liner and 11 were in the diet control group. The EndoBarrier was implanted for 12 weeks and some of these patients were allowed to continue for an additional 12 weeks. Four patients continued beyond the initial 12 weeks. Patients in both the EndoBarrier and diet control groups followed the same diet during the study period. Starting average weight for these two groups was similar with 142.3 kg (313 lbs) for EndoBarrier patients versus 137.5 kg (303.2 lbs) for control group patients, and body mass index (BMI) of 48.2 versus 49.2, respectively.

The data show that at three months, EndoBarrier patients experienced a mean excess weight loss of 19.0% versus 6.9% ($p < 0.001$) in the diet control group. In the eight patients with type 2 diabetes, all improved dramatically during the study period as evidence by the decrease in blood glucose levels and a reduction in diabetic medication. The mean procedure time was 33 minutes for device implants and 15 minutes for device explants. There were no procedure related adverse events.

These results further support the clinical findings of the first human experience with the EndoBarrier which were published in *Surgery for Obesity and Related Diseases* in 2008. That study, a 12-patient prospective, open-label, single center, 12-week trial, found that the EndoBarrier had a favorable safety and encouraging efficacy profile, and could be safely delivered and removed endoscopically and left in place for 12 weeks. The average percentage of excess weight loss for the 10 patients with the device was 23.6%, with all patients achieving at least 10% excess weight loss. All four diabetic patients had normal fasting plasma glucose levels without hypoglycemic medication for the entire 12 weeks. Of these four patients, three had a clinically meaningful decrease of HbA1c levels of <http://www.businesswire.com/portal/s...>

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greater than or equal to 0.5% by week 12.

"We are extremely encouraged by these findings which are in line with our earlier clinical studies as well as our preclinical studies," said Stuart A. Randle, chief executive officer of GI Dynamics. "The data demonstrate that patients with the EndoBarrier can achieve clinically meaningful weight loss and immediate normalization of blood glucose levels. The metabolic effects that we are seeing are similar to the effects seen after gastric bypass surgery but without the risks associated with surgery. We look forward to studying the device further and continuing longer term studies in patients who suffer from obesity and type 2 diabetes."

Obesity is a metabolic disease affecting 70 million people in the US alone. The World Health Organization (WHO) estimates that the number of overweight adults worldwide will rise to 2.3 billion by 2015 from 1.6 billion today, and obesity levels will rise to 700 million from 400 million. According to the WHO, a person is overweight if they have a BMI (body-mass index, a ratio of height to weight) equal to or more than 25, and is considered obese if their BMI is equal to or more than 30. Obesity is a complex metabolic disorder that is commonly associated with type 2 diabetes, hypertension, coronary heart disease, stroke, gallbladder disease, stroke, and cancer.

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.

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