Early Results: Gastrointestinal Liner May Help Treat Obesity, Type 2 Diabetes

GI Dynamics announces initial, positive results from a clinical trial evaluating 12 months of treatment with the EndoBarrier™ Gastrointestinal Liner. The first group of patients from this trial have successfully completed 12 months, or 52 weeks, of treatment with the EndoBarrier Gastrointestinal Liner, an important milestone in the clinical development of this non-surgical therapeutic. The clinical trial was led by Eduardo G. Moura, M.D., Ph.D., director of endoscopy, digestive surgery department, Hospital das Clinicas, University of Sao Paulo, Brazil.

“This is a landmark achievement for the EndoBarrier and GI Dynamics” “Successful 12-month implantation with the EndoBarrier is a clinically important achievement and a promising indicator that this non-surgical medical device may offer our patients an innovative new solution to simultaneously combat both type 2 diabetes and obesity,” commented Keith Gersin, M.D., FACS, chief of bariatric surgery at Carolinas Medical Center and chief medical director of GI Dynamics. “The data we have seen previously in patients treated for up to six months is very compelling, and these data from 52 weeks of treatment further extend the potential impact and efficacy of this approach. I look forward to the full data set from this trial as the rest of the patients complete the 12-month mark.”

The 52-week trial was designed to evaluate the EndoBarrier Gastrointestinal Liner in 22 obese patients with type 2 diabetes. The primary endpoints in the trial include improvement in type 2 diabetes and excess weight loss. To date, the first six of the 22 subjects implanted with the EndoBarrier have successfully reached the 52-week endpoint.

The average baseline weight for the subjects was 270.5 lbs (± 22.2 1bs), average baseline HbA1c was 9.3% (± 0.8%) and subjects were taking oral anti-diabetes medications. Top-line results for the first six subjects show that on average patients achieved the following results:

- HbA1c decrease of 2.5% (± 0.6%) with 5 of the 6 getting below 7.0%
- 25.9 % excess body weight loss (± 4.6%)
- 35.5 lbs weight loss (± 9 lbs)

“This is a landmark achievement for the EndoBarrier and GI Dynamics,” said Stuart A. Randle, chief executive officer of GI Dynamics. “I want to congratulate and thank our technical, clinical and scientific teams for their efforts which have led us to a successful 12-month device design and the meaningful results we have observed

clinically to-date. We believe that EndoBarrier is well positioned to provide a transformative alternative to pharmaceutical and surgical methods for treating type 2 diabetes and obesity. This milestone further enhances the potential clinical value of the EndoBarrier offering."

The EndoBarrier, a non-surgical therapy to treat type 2 diabetes and obesity, received European CE mark approval for the treatment of type 2 diabetes and obesity in December 2009. Clinical trials to date involving more than 280 patients have demonstrated the significant weight loss and diabetes improvement achieved with the EndoBarrier Gastrointestinal Liner.

Type 2 diabetes affects an estimated 21 million Americans and 200 million people worldwide. According to the World Health Organization, type 2 diabetes comprises 90% of people with diabetes around the world, and is largely the result of excess body weight. Type 2 diabetes can lead to significant health problems including cardiovascular disease, retinopathy, neuropathy and nephropathy.

GI Dynamics is defining a new class of metabolic treatment options that fit between pharmaceutical regimens and surgery, called non-surgical therapeutics. Non-surgical therapeutics are designed to eliminate or reduce the risks and side effects associated with pharmaceutical regimens as well as surgical options. This new class of treatment can be performed easily and quickly without any incisions, thus reducing patient anxiety and recuperative time.

Unlike traditional pharmaceutical approaches, non-surgical therapeutics remove the burden of dose regimen compliance from the patient. Additionally, non-surgical therapeutics hold the potential to improve the patient's overall health, by providing the control necessary to institute lifestyle and nutritional improvements to maintain therapeutic effect, while being easily removed once the desired effect has been attained and lifestyle changes implemented.

The patented EndoBarrier Gastrointestinal Liner is an advanced investigational, non-surgical medical device based on the EndoBarrier Technology platform for treating type 2 diabetes and obesity. The EndoBarrier Gastrointestinal Liner is placed in the GI tract endoscopically (via the mouth) to create a barrier between food and the wall of the intestine.

Physicians believe that preventing food from coming into contact with the intestinal wall may alter the activation of hormonal signals that originate in the intestine, thus mimicking the effects of a Roux-en-Y gastric bypass procedure without surgery.

A growing body of preclinical and clinical evidence supports the potential for EndoBarrier Gastrointestinal Liner to change the treatment landscape for people living with type 2 diabetes, obese people at risk for type 2 diabetes, and people with severe weight problems.

For more information, visit GI Dynamics online at www.gidynamics.com [1]

Source: Business Wire

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http://www.surgicalproductsmag.com/news/2010/03/early-results-gastrointestinal-liner-may-help-treat-obesity-type-2-diabetes?qt-recent_videos=0

Links:
[1] http://www.gidynamics.com/