GI Dynamics announces results of EndoBarrier® Therapy studies at Digestive Disease Week meeting

- EndoBarrier mechanism-of-action study shows ~18 kg mean weight loss and negative correlation between fat absorption and weight loss
- EndoBarrier treatment shows reduction in hepatic fat of 81% and 6x liraglutide effect, an initial indication that EndoBarrier may reduce hepatic fat

LEXINGTON, Mass. and SYDNEY, Australia – 13 June 2016 – GI Dynamics, Inc. (ASX:GID), a medical device company that has developed an innovative endoscopically delivered treatment for type 2 diabetes and obesity, today announced the results of clinical studies involving EndoBarrier Therapy that were presented during Digestive Disease Week, the annual meeting of the American Gastroenterological Association.

The presentations summarized below represent investigator-initiated studies.

- **Endoscopic treatment of obesity with a duodenal-jejunal bypass sleeve: Does impairment of fat absorption explain weight loss?**
  Gerald Holtmann, M.D., Ph.D., et al., School of Medicine, University of Queensland, Brisbane, Australia

  This study assessed changes in fat absorption and meal-related symptoms before and after EndoBarrier implantation in obese type 2 diabetes patients, and also analyzed the correlation between these factors and weight loss.

  Interim results after 34 weeks of implant duration showed a median weight loss of 18.2 kg (40 lbs.) or 15.5% total body-weight loss. The intensity of meal-related dyspepsia (indigestion) was seen as positively correlated to weight loss. There was no correlation between weight loss and fat absorption, indicating that the reduction in weight and HbA1c achieved with EndoBarrier Therapy were not the result of fat malabsorption.

  To view the abstract, visit [http://www.ddw.org/program/online-planner](http://www.ddw.org/program/online-planner), click “Abstract” from the menu bar and enter session number Su1976.

- **Endoscopic proximal intestinal exclusion can improve non-alcoholic fatty liver disease (NAFLD) in patients with diabesity**
  Bu Hayee, Ph.D., King’s College Hospital NHS Foundation Trust, London, U.K.

  This study investigated the impact of EndoBarrier Therapy (EBT) on non-alcoholic fatty liver disease (NAFLD) with or without an additional GLP-1 receptor agonist (liraglutide), a non-insulin medicine prescribed to lower blood sugar levels.

1 Holtmann, et al.
2 Hayee, et al.
Seventy adults with uncontrolled type 2 diabetes and obesity who had been taking 1.2 mg of liraglutide daily were randomized into three treatment groups:

- EndoBarrier Therapy plus liraglutide (1.2 mg)
- EndoBarrier Therapy only
- Liraglutide alone with an escalated dose (1.8 mg daily)

Changes in weight, hemoglobin A1C (HbA1c) and NAFLD fibrosis score (NFS) were calculated over three months within groups. A subset of EBT subjects underwent magnetic resonance imaging (MRI) to quantify hepatic fat prior to and four months after completing EndoBarrier Therapy.

NFS scores for study subjects categorized as high risk for NAFLD were reduced for both EBT groups (33% and 35%, respectively, to 14%), but not for the liraglutide-only group. The cohort of EBT subjects that underwent MRI four months post-EndoBarrier removal experienced an 80.5% reduction (from 14.9% to 2.9%) in hepatic fat.

Despite previous suboptimal response to liraglutide treatment, EndoBarrier Therapy was effective at reducing hepatic fat. These data suggest that EndoBarrier Therapy may be an effective future treatment for patients with NAFLD.

To view the abstract, visit [http://www.ddw.org/program/online-planner](http://www.ddw.org/program/online-planner), click "Abstract" from menu bar and enter session number Su 951.

“We’re very pleased that EndoBarrier Therapy was well represented at Digestive Disease Week this year,” stated Scott Schorer, president and CEO of GI Dynamics, Inc. “These studies add to the body of clinical evidence supporting the safety and efficacy of EndoBarrier Therapy for treating obese type 2 diabetes. Further to that, they advance our understanding of EndoBarrier Therapy’s mechanism of action and its effect on NAFLD.

“I would like to thank Drs. Hayee and Holtmann and their esteemed colleagues for their continued contribution to the science of EndoBarrier Therapy.”

**About GI Dynamics**

GI Dynamics, Inc. (ASX: GID) is the developer of EndoBarrier®, the first endoscopically delivered device therapy approved for the treatment of type 2 diabetes and obesity. EndoBarrier is approved and commercially available in multiple countries outside the United States. EndoBarrier is not approved for sale in the United States and is limited by federal law to investigational use only in the United States. Founded in 2003, GI Dynamics is headquartered in Lexington, Massachusetts. For more information, please visit [www.gidynamics.com](http://www.gidynamics.com).

**Forward-Looking Statements**

This announcement contains forward-looking statements concerning: our development and commercialization plans; our potential revenues and revenue growth, costs, excess inventory, profitability and financial performance; our ability to obtain reimbursement for our products; our clinical trials, and associated regulatory submissions and approvals; the number and location of commercial centers offering the EndoBarrier; and our intellectual property position. These forward-looking statements are based on the current estimates and expectations of future events by the management of GI Dynamics.
Inc. as of the date of this announcement and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those indicated in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: risks associated with the consequences of terminating the ENDO Trial and the possibility that future clinical trials will not be successful or confirm earlier results; risks associated with obtaining funding from third parties; risks relating to the timing and costs of clinical trials, the timing of regulatory submissions, the timing, receipt and maintenance of regulatory approvals, the timing and amount of other expenses, and the timing and extent of third-party reimbursement; risks associated with commercial product sales, including product performance; competition; risks related to market acceptance of products; intellectual property risks; risks related to excess inventory; risks related to assumptions regarding the size of the available market, benefits of our products, product pricing, timing of product launches, future financial results and other factors including those described in our filings with the U.S. Securities and Exchange Commission. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We do not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.