



GI Dynamics, Inc. – ASX Announcement

## **GI Dynamics Announces Results of First Comparative Study of Gastric Bypass and EndoBarrier® Therapy on Diabetes Remission at Digestive Disease Week 2015**

**LEXINGTON, Massachusetts, United States and SYDNEY, Australia – 19 May 2015 – [GI Dynamics, Inc.](#) (ASX: **GID**)**, a medical device company providing innovative treatments for type 2 diabetes and obesity, today announced data showing improvement in glucose metabolism following treatment with EndoBarrier® Therapy (duodenal-jejunal bypass liner or DJBL) that comes significantly close to improvement achieved with gastric bypass surgery (RYGB) in obese patients with type 2 diabetes. In a poster titled, 'Improvement in Glucose Metabolism after Bariatric Surgery: Comparison of Laparoscopic Roux-en-Y Gastric Bypass and Duodenojejunal Bypass,' Dr. Jürgen Stein, Department of Gastroenterology and Clinical Nutrition, Hospital Sachsenhausen, Frankfurt, Germany, presented these findings at the American Gastroenterological Association's annual Digestive Disease Week (DDW) meeting in Washington, D.C.

This is the first study comparing the improvement in glucose metabolism following gastric bypass surgery, considered the 'gold standard' of metabolic surgery, to the less invasive endoscopic placement of the EndoBarrier device. Preliminary data demonstrate that both procedures have a similar impact on diabetes remission and significant impact on body weight: RYGB ( $\Delta$  HbA<sub>1c</sub>, -1.1%,  $\Delta$  bw – 28.2 kg;  $\Delta$  BMI – 10.4 kg/m<sup>2</sup>), DJBL ( $\Delta$  HbA<sub>1c</sub>, -1.4%,  $\Delta$  bw – 22.9 kg;  $\Delta$  BMI – 8.8 kg/m<sup>2</sup>).

"It is interesting to observe how EndoBarrier treatment compares to bariatric surgery when administered at the same clinical center in the hands of independent researchers," said David Maggs, M.D., chief medical officer of GI Dynamics. "This is another important milestone that manifests the potential for device intervention while avoiding the alteration of anatomy by surgery."

These data show that EndoBarrier, specifically designed to mimic the duodenal-jejunal exclusion created by gastric bypass surgery, has a significant impact on glucose homeostasis at one, three and nine months of therapy, which can reduce the reliance patients may have on diabetes medications.

### **About GI Dynamics**

GI Dynamics, Inc. (ASX: GID) is the developer of EndoBarrier®, the first endoscopically-delivered device therapy approved for the treatment of obese type 2 diabetes with BMI  $\geq 30$  kg/m<sup>2</sup>, or obese patients with BMI  $\geq 30$  kg/m<sup>2</sup> with  $\geq 1$  comorbidities, or obese patients with BMI  $>35$  kg/m<sup>2</sup>. The liner is indicated for a maximum implant duration of 12 months. EndoBarrier is approved and commercially available in multiple countries outside the U.S. EndoBarrier is not approved for sale in the U.S. and is limited by federal law to investigational use only in the United States. GI Dynamics is conducting a pivotal clinical trial of EndoBarrier in the U.S. for the treatment of patients who have uncontrolled type 2 diabetes and are obese. 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 centres 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

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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 possibility that 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.

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