

GI Dynamics, Inc. - ASX Announcement

## FOR IMMEDIATE RELEASE

## New Data Presented at EASD Demonstrate Robust Cardiometabolic Health Effects of EndoBarrier® Therapy in Obese People With and Without Diabetes

Pooled analysis from two studies shows significant reduction in 10-year CV risk

LEXINGTON, Massachusetts & SYDNEY, Australia – 17 September 2014 – GI Dynamics, Inc. (ASX: GID), a medical device company developing innovative treatments for type 2 diabetes and obesity, today announced new data demonstrating clinically meaningful improvements in the prevalence of metabolic syndrome, as well as a reduction in 10-year cardiovascular (CV) risk in obese patients treated with <a href="EndoBarrier® Therapy">EndoBarrier® Therapy</a>. Robert J. Chilton, D.O., F.A.C.C., professor, Department of Medicine, Division of Cardiology, University of Texas Health Science Center at San Antonio, presented these findings during a poster presentation at the 50th Annual Meeting of the European Association for the Study of Diabetes (EASD) in Vienna, Austria.

"The findings from our pooled analysis demonstrated that EndoBarrier Therapy for obese patients with and without diabetes, resulted in significant improvements in body weight, glycemic control and multiple cardiometabolic risk factors, which translated to a consistent reduction in the patients' 10-year estimated CV risk, using three well-known CV risk models," said Dr. Chilton. "While further exploration is warranted, EndoBarrier Therapy appears to be an effective tool to rapidly improve a patient's cardiometabolic health, offering clinicians an adjunctive approach to currently available pharmacotherapy and an alternative to existing surgical options."

The findings were from two clinical studies of EndoBarrier involving a total of 40 obese patients with and without type 2 diabetes who completed 12 months of treatment with EndoBarrier Therapy. Results showed that during treatment, the overall cohort lost an average of 18.6% in total body weight and 17.7 cm from the waist. Additionally, systolic blood pressure dropped by 7.6 mmHg, LDL-cholesterol decreased by 0.6 mmol/L, and HbA1c levels were reduced by an average of 2.1% in the diabetic subgroup (n=20). Given these improvements, the number of patients who met the criteria for metabolic syndrome<sup>1</sup> at the time of EndoBarrier implant (35/40) was reduced by 37% (20/40). Importantly, the use of EndoBarrier Therapy also resulted in a 19-40% reduction in 10-year CV risk level, as calculated by three different CV risk models.

In addition, four other scientific posters highlighting EndoBarrier Therapy were presented during EASD, including data from Andrew Young, M.D., Ph.D., vice president, head of Endocrine Biology, GlaxoSmithKline. These findings, which build on earlier data presented at Digestive Disease Week 2014, demonstrate that implantation of the EndoBarrier device in morbidly obese

<sup>&</sup>lt;sup>1</sup> As defined by the National Cholesterol Education Program's Adult Treatment Panel III report (ATP III)

patients with and without type 2 diabetes resulted in increased circulating bile acids, similar to the increase observed in gastric bypass procedures. Such findings may provide some hypothesis as to the EndoBarrier's potential mechanism of action.

"Type 2 diabetes and obesity pose a growing challenge in clinical practice, and we believe EndoBarrier Therapy represents an important advancement in addressing these dual epidemics," said David Maggs, M.D., chief medical officer of GI Dynamics. "The body of evidence supporting the use of EndoBarrier Therapy continues to grow, not only for its ability to improve type 2 diabetes and obesity, but also for its impact on overall cardiometabolic health."

## **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/or obesity. 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 <a href="https://www.gidynamics.com">www.gidynamics.com</a>.

## **Forward-Looking Statements**

This presentation contains forward-looking statements based on the current estimates and expectations of future events by the management of GI Dynamics, Inc. as of the date of this presentation 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. Generally, you can identify forward-looking statements by terms such as "may", "will", "should", "could", "expects", "plans", "anticipates", "believes", "estimates", "projects", "predicts", "potential" and other similar expressions that are intended to identify forward-looking statements, which are generally not historical in nature. All statements that address operating performance, events or developments that GI Dynamics expects or anticipates will occur in the future are forward-looking statements. These risks and uncertainties include, but are not limited to: risks associated with estimates of potential revenues; the number and location of commercial centers offering the EndoBarrier®; ability to obtain and maintain regulatory approval for our products; ability to obtain and maintain third-party reimbursement for our products; performance and acceptance of our product, competition; product costs, the timing, costs and outcomes of clinical trials including our pivotal trial; intellectual property risks; risks associated with obtaining funding from third parties; future financial results and other factors including those described in our filings with the U.S. Securities and Exchange Commission and the Australian Securities Exchange. 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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