# Association of British Clinical Diabetologists Releases First Worldwide EndoBarrier Benefit – Risk Report

Boston, United States
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**BOSTON and SYDNEY — 9 July 2018 —** GI Dynamics® Inc. (ASX: GID), a medical device company that is developing EndoBarrier® for patients diagnosed with type 2 diabetes and obesity, is pleased to announce the first report from the Association of British Clinical Diabetologists (ABCD) Worldwide EndoBarrier Registry evaluating the benefit – risk of EndoBarrier, presented by Robert Ryder, MD of Sandwell and West Birmingham Hospitals at the American Diabetes Association's 78th Scientific Sessions.

The study, "First Risk-Benefit Data from the Worldwide EndoBarrier Registry," demonstrates the value EndoBarrier provides for patients diagnosed with type 2 diabetes and obesity. The registry has gathered data from more than 400 patients in 13 centers across four countries, nearly doubling the data collection rate since last year.

For patients dealing with type 2 diabetes and obesity, lowering weight, HbA1c, blood pressure and medication dosage presents significant challenges. The initial report from the ABCD Worldwide EndoBarrier Registry indicates that EndoBarrier is safe and effective in addressing these significant health issues.

## Benefit

This registry shows a mean reduction of 1.5 percent absolute HbA1c and ~15kg weight loss, with associated improvements including reduction of blood pressure.

| Parameter | n | Baseline | Explant | Difference | P-value |
|---|---|---|---|---|---|
| Weight (kg) | 256 | 125 | 111 | 14 | < 0.001 |
| HbA1c (%) | 195 | 8.7 | 7.2 | 1.5 | < 0.001 |
| Systolic Blood Pressure (mmHg) | 149 | 139 | 130 | 9 | < 0.001 |

*n = patient population*

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When comparing HbA1c outcomes, many patients ranged from those with no diagnosis of type 2 diabetes to those diagnosed with advanced type 2 diabetes and high HbA1c. The study indicates a direct correlation between higher starting HbA1c and reduction in HbA1c.

Reduction in HbA1c based on starting HbA1c:

| HbA1c Range (%) | n | Baseline, Mean % | Explant, Mean % | Difference, Absolute % | P-value |
|---|---|---|---|---|---|
| All HbA1c | 195 | 8.7 | 7.2 | 1.5 | < 0.001 |
| All HbA1c ≥ 7 | 162 | 9.1 | 7.4 | 1.7 | < 0.001 |
| All HbA1c ≥ 7.5 | 144 | 9.4 | 7.5 | 1.9 | < 0.001 |
| All HbA1c ≥ 8 | 116 | 9.8 | 7.7 | 2.1 | < 0.001 |
| All HbA1c ≥ 9 | 71 | 10.7 | 7.8 | 2.9 | < 0.001 |

Reduction in HbA1c based on ranges > 8% starting HbA1c:

| HbA1c Range (%) | n | Baseline, Mean % | Explant, Mean % | Difference, Absolute % | P-value |
|---|---|---|---|---|---|
| HbA1c ≥ 8-10 | 73 | 8.8 | 7.5 | 1.3 | < 0.001 |
| HbA1c ≥ 8-10.5 | 83 | 9 | 7.5 | 1.5 | < 0.001 |
| HbA1c ≥ 8-11 | 89 | 9.1 | 7.6 | 1.5 | < 0.001 |
| HbA1c ≥ 8-12 | 104 | 9.4 | 7.7 | 1.7 | < 0.001 |

**Risk**

The registry shows a serious adverse event (SAE) rate of 5.7 percent with the majority being gastrointestinal bleeds, at a rate of 3.7 percent. Dr. Ryder also explained that the hepatic abscess rate in this study was noticeably lower than the rate in the United States pivotal trial. All patients with a SAE made a full recovery and many even experienced considerable benefit despite complications during treatment.

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“This data from the ABCD Worldwide EndoBarrier Registry suggests that the benefits of EndoBarrier treatment far outweigh the risks,” said Dr. Ryder. “Our patients are enthusiastic about what EndoBarrier has done for them. Many of those who faced complications still experienced health benefits.”

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"Type 2 diabetes and obesity are affecting the world's population at an alarming rate, with many people unable to manage their health issues using current available treatment options," said Scott Schorer, president and chief executive officer of GI Dynamics. "EndoBarrier is proving to be a positive alternative to other treatment options available and remains one of the few options other than pharmacotherapy or gastric bypass for patients with type 2 diabetes and obesity."

**About GI Dynamics**

GI Dynamics®, Inc. (ASX:GID) is the developer of EndoBarrier®, the first endoscopically-delivered device therapy for the treatment of type 2 diabetes and obesity. EndoBarrier is not approved for sale and is limited by federal law to investigational use only. Founded in 2003, GI Dynamics is headquartered in Boston, Massachusetts. For more information please visit gidynamics.com.

**Forward-Looking Statements**

This announcement may contain forward-looking statements. These forward-looking statements are based on GI Dynamics management's current estimates and expectations of future events as of the date of this announcement. Furthermore, the estimates are subject to several 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 our ability to continue to operate as a going concern, our ability to maintain compliance with our obligations under the Convertible Loan Note executed with Crystal Amber Fund Limited, obtaining and maintaining regulatory approvals required to market and sell our products; obtaining funding from third parties; the consequences of stopping the ENDO trial and the possibility that future clinical trials will not be successful or confirm earlier results; 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; the timing and extent of third-party reimbursement; intellectual-property risk; risks related to excess inventory; and

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risks related to assumptions regarding the size of the available market, the 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, one 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 or future events or otherwise, unless we are required to do so by law.

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