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# UK National Health Service EndoBarrier Service Releases Final Data of One-Year Outcome

**BOSTON and SYDNEY — 15 March 2019 —** GI Dynamics® Inc. (ASX:GID), a medical device company that is developing EndoBarrier® for patients with type 2 diabetes and obesity, is pleased to announce positive results on final data from the United Kingdom's National Health Service (NHS) EndoBarrier Service. Principal investigator Robert Ryder, M.D., of Sandwell and West Birmingham Hospitals presented the results at the Diabetes UK Professional Conference 2019 in Liverpool last week. The data show a significant reduction in HbA1c, weight, liver fat and cardiovascular disease (CVD) risks as well as a reduction in the need for insulin in some patients.

This study, titled "UK First NHS EndoBarrier Service for Advanced Type 2 Diabetes and Obesity: One-Year Outcomes in All Patients Treated," is based on data collected from the first implant in October 2014 to the last explant in November 2018, a total patient population of 61.

The primary outcome of HbA1c, weight, CVD risk factors and alanine aminotransferase (ALT — a liver fat measure) show a significant reduction at explant compared to baseline values. Of the 61 patients studied, 35 were on insulin prior to treatment. At explant, 10 of the 35 (28.6 percent) discontinued their use of insulin.

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| Parameter | n | Baseline | Explant | Difference | P-value |
|---|---|---|---|---|---|
| **HbA1c** (mmol/mol) | 61 | 80.2 ± 22.5 | 56.5 ± 11.5 | ↓23.7 ± 21.4 | <0.001 |
| **HbA1c** (%) | 61 | 9.5 ± 2.1 | 7.3 ± 1.1 | ↓2.2 ± 2.0 | <0.001 |
| **Weight** (kg) | 61 | 122.6 ± 27.9 | 106.7 ± 28.9 | ↓15.9 ± 8.5 | <0.001 |
| **BMI** ($kg/m^2$) | 61 | 41.9 ± 7.4 | 36.2 ± 7.6 | ↓5.7 ± 3.2 | <0.001 |
| **Systolic Blood Pressure** (mmHg) | 61 | 138.5 ± 15.0 | 125.8 ± 14.6 | ↓12.7 ± 16.2 | <0.001 |
| **Cholesterol** (mmol/L) | 61 | 4.7 ± 1.4 | 3.9 ± 0.9 | ↓0.86 ± 1.13 | <0.001 |
| **HDL** (mmol/L) | 61 | 1.13 ± 0.27 | 1.10 ± 0.30 | ↓0.04 ± 0.22 | 0.135 |
| **ALT** (U/l) | 61 | 33.2 ± 19.8 | 19.5 ± 11.4 | ↓13.7 ± 20.1 | <0.001 |
| **Insulin Daily Dose** (Median (IQR)) | 35 | 100 (60 - 135) | 40 (0 - 70) | ↓60 | <0.001 |

The most significant outcome measure is the 2.2 absolute percent reduction of HbA1c at 12 months with a concurrent weight loss of 15.9 kg (35 lbs.), highlighting the dual primary treatment effect of EndoBarrier.

Ryder input all data from this study into the UK Prospective Diabetes Study (UKPDS) Risk Engine provided by the Diabetes Trials Unit of The Oxford Centre for Diabetes, Endocrinology and Metabolism. Through that evaluation, Ryder analyzed the potential impact of EndoBarrier on 10-year CVD risk for patients with type 2 diabetes and obesity.

| Parameter | Baseline | Explant | P-value | Absolute Risk Reduction | Cases Saved (out of 100) | Numbers Needed to Treat |
|---|---|---|---|---|---|---|
| CHD | 15.8 ± 11.8 | 9.0 ± 6.0 | <0.001 | ↓6.8 ± 7.6 | 6.8 | 14.7 |
| Fatal CHD | 11.4 ± 10.1 | 5.6 ± 4.7 | <0.001 | ↓5.7 ± 6.7 | 5.7 | 17.5 |
| Stroke | 5.90 ± 4.71 | 4.84 ± 3.70 | <0.001 | ↓1.06 ± 1.50 | 1.06 | 94.3 |
| Fatal Stroke | 0.94 ± 0.89 | 0.61 ± 0.52 | <0.001 | ↓0.33 ± 0.54 | 0.33 | 303.0 |

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Utilizing the UKPDS Risk Engine and clinical results from EndoBarrier in this study, approximately 8 of 100 patients would avoid coronary heart disease or a stroke event over the next 10 years.

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"We are pleased to share the final outcome from this study, which suggests EndoBarrier can provide significant improvements for patients with long-standing poorly controlled diabetes and obesity, who have been unable to manage their diabetes with standard treatment options," said Ryder. "Further evidence and research suggest EndoBarrier contributes to the reduction of other comorbidities associated with type 2 diabetes and obesity."

"This expanded data set from the NHS EndoBarrier Service continues to develop the breadth of support for clinical efficacy of EndoBarrier in a real-world clinical setting," said Scott Schorer, president and chief executive officer. "The significant reduction of HbA1c, weight and improvement in numerous markers — including reduction in cardiovascular risk and elimination of insulin use for 28 percent of patients — is substantial."

**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 www.gidynamics.com.

**Forward-Looking Statements**

This announcement may contain forward-looking statements. These 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 raise sufficient additional funds to continue operations and to conduct the planned pivotal trial of EndoBarrier in

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the United States (18-1 study); our ability to execute the 18-1 study under FDA's Investigational Device Exemption; our ability to enlist clinical trial sites and enroll patients in accordance with the 18-1 study; the risk that the FDA stops the 18-1 study early as a result of the occurrence of certain safety events or does not approve an expansion of the 18-1 study; our ability to maintain compliance with our obligations under our existing convertible note and warrant agreements executed with Crystal Amber Fund Limited, including our obligations to make payment on the relevant note that is due in March 2019; our ability to restructure the terms of the convertible note with Crystal Amber Fund Limited that is due in March 2019 if we are unable to raise sufficient funds to enable us to fully repay such note when due; obtaining and maintaining regulatory approvals required to market and sell our products; 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; 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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