# EndoBarrier Meta-Analysis
# Published in Diabetes Care Journal

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**BOSTON and SYDNEY – 10 May 2018 —** 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 the meta-analysis, "Effects of the Duodenal-Jejunal Bypass Liner on Glycemic Control in Type 2 Diabetic Patients with Obesity: A Meta-analysis with Secondary Analysis on Weight Loss and Hormonal Changes," by Pichamol Jirapinyo, MD, of Brigham and Women's Hospital in Boston, Massachusetts, and Diplomat of the American Board of Obesity Medicine, has been published in Diabetes Care, the journal of the American Diabetes Association.

The meta-analysis is comprised of 17 published studies that evaluate EndoBarrier (also referred to as duodenal-jejunal bypass liner [DJBL]) outcomes in patients with type 2 diabetes and obesity. The primary outcomes of the meta-analysis were change in hemoglobin A1c (HbA1c) and homeostatic model assessment of insulin resistance (HOMA-IR). Secondary outcomes were change in weight and change in hormones critical to the regulation of metabolic and bariatric disorders: GIP[1], GLP-1[2], PYY[3] and ghrelin.

"The analysis shows that DJBL is effective at treating diabetes in this patient population with a reduction in HbA1c of 1.3%, and with many patients coming off diabetic medication," said Jirapinyo. "This reduction in HbA1c is significantly better by 0.9% as compared to optimal medical management alone. In addition, this study demonstrates that patients who receive DJBL experience significant improvements in insulin resistance and weight loss, which persist up to at least six months after device removal."

Jirapinyo's study also highlighted a clinically and statistically significant improvement in insulin resistance.

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[1] GIP: glucose-dependent insulinotropic peptide
[2] GLP-1: glucagon-likepeptide1
[3] PYY: peptide YY

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| | | | Change from Baseline | # studies | n | p value |
|---|---|---|---|---|---|---|
| HbA1c | HbA1c | | | | | |
| | HbA1c | (% absolute) | -1.3% | 14 | 388 | < 0.0001 |
| | HbA1c v Control | (% absolute) | -0.9% | 4 | 116 | < 0.0001 |
| | 6 months post removal | | | | | |
| | HbA1c | (% absolute) | -0.9% | 4 | 120 | <0.0001 |
| IR | Insulin Resistance | | | | | |
| | HOMA-IR | | -4.6 | 5 | 91 | < 0.0001 |
| Weight | Weight | | | | | |
| | Weight | (kg) | -11.3 | 10 | 352 | <0.0001 |
| | Total Weight Loss | (%) | 18.9% | 4 | 305 | 0.002 |
| | Excess Weight Loss | (%) | 36.9% | 4 | 301 | <0.0001 |
| | 12 months post removal | | | | | |
| | Total Weight Loss | (%) | 7.2% | 2 | 80 | <0.0001 |

**All data is statistically significant.*

Jirapinyo conducted this study according to the PRISMA[4] statement and reviewed over 1,000 published EndoBarrier studies. Following strict inclusion and exclusion methodologies which were defined *a priori*, a total of 17 published studies were included in the final meta-analysis. Jirapinyo contacted authors for additional information that was needed, which contributed to making the study robust and comprehensive.

“Given a rising pandemic of obesity and diabetes, DJBL may offer a highly effective treatment option for this patient population,” said Jirapinyo.

“We are pleased to review the results from this comprehensive EndoBarrier meta-analysis that Dr. Jirapinyo and the clinical team at Harvard Medical School and Brigham and Women’s Hospital conducted,” said Scott Schorer, GI Dynamics president and chief executive officer. “The results confirm that EndoBarrier produces a significant reduction in HbA1c and weight, significantly reduces insulin resistance and creates a hormonal effect similar in many respects to gastric bypass.”

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[4] PRISMA: an evidence-based minimum set of items for reporting in systematic reviews and meta-analyses

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"This data clearly shows a very favorable treatment effect with significant treatment durability and a positive benefit-risk profile," said Schorer. "This study presents the most comprehensive EndoBarrier meta-analysis we have seen and this type of data is indicative of EndoBarrier's highly impactful clinical utility."

## 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 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 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

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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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