Boston, United States
Sydney, Australia
14 June 2019 AEST

EndoBarrier Sleep Apnea Study Shows Significant Improvements Sustained Post Explant

BOSTON and SYDNEY — 14 June 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 data presented at the American Diabetes Association's 79th Scientific Sessions in San Francisco, California. Mahender Yadagiri, M.D. of City Hospital in Birmingham, U.K. presented "EndoBarrier in Type 2 Diabetes/Pre-Diabetes with Obstructive Sleep Apnoea (OSA) Study – Maintenance of Improvement after EndoBarrier Removal," otherwise known as the End-OSA study.

The End-OSA study is a single-center clinical trial, initiated and funded by the Association of British Clinical Diabetologists (ABCD) based in City Hospital of Sandwell and West Birmingham Hospitals, Birmingham, U.K. It is a clinical investigational study of EndoBarrier used to treat patients with moderate obstructive sleep apnea (OSA) who have type 2 diabetes or pre-diabetes over a 24-month period. Patients were implanted with EndoBarrier for up to 12 months, followed by additional clinical visits to gather post explant data for up to 12 months after EndoBarrier explantation.

Patients included in the study had moderate OSA [Apnea Hypopnea Index (AHI) 15 – 29 events/hour] treated with continuous positive airway pressure (CPAP), type 2 diabetes or pre-diabetes, obesity (BMI ≥30 and ≤45 kg/m^2) and ≥18 years of age. The End-OSA study's primary endpoint was the reduction in number of AHI events – the sum of hypopneas and apneas as measured by average occurrence each hour of rest.

Investor Relations
United States:
Janell Shields
+1 (781) 357-3280
investor@gidynamics.com

Boston, United States
Sydney, Australia
14 June 2019 AEST

Parameter	At Baseline	At Explant	Difference from Baseline
AHI (events/hr)	18.8	10.6	↓ 8.2
HbA1c (absolute %)	7.7	6.6	↓ 1.1
Weight (Kg)	104.9	93.8	↓ 11.1
BMI (Kg/M^2)	38.0	33.9	↓ 4.1
Systolic BP (mm Hg)	129.3	121.2	↓ 8.1

Parameter	At Baseline	Latest Post Explant Data	Difference from Baseline
AHI (events/hr)	18.8	9.1	↓ 9.7
HbA1c (absolute %)	7.7	6.9	↓ 0.8
Weight (Kg)	104.9	92.9	↓ 12.0
BMI (Kg/M^2)	38.0	33.5	↓ 4.5
Systolic BP (mm Hg)	129.3	126.6	↓ 2.7

AHI = Apnea Hypopnea Index
Systolic BP = Systolic Blood Pressure

The data shows significant improvements in AHI events per hour, HbA1c, weight, and BMI. During EndoBarrier treatment, all 10 patients were able to decrease their AHI events from a mean of 18.8 events per hour to below 15 events per hour, putting them below the threshold to require CPAP per the National Institute for Health and Care Excellence (NICE) guidelines.

The follow-up data was collected at a mean (range) of 9.7 (3 – 17.6) months after EndoBarrier explant. At this latest data point, AHI was below 15 events per hour for all patients such that they remained off CPAP.

Investor Relations
United States:
Janell Shields
+1 (781) 357-3280
investor@gidynamics.com

“These results confirm previously demonstrated metabolic improvements from EndoBarrier in diabesity and demonstrate major benefit for patients with moderate OSA,”

Boston, United States
Sydney, Australia
14 June 2019 AEST

said Dr. Yadagiri. “Discontinuing CPAP is not only beneficial to health services but especially to patients.”

“The End-OSA study highlights one of the clinical effects on a comorbidity associated with type 2 diabetes and obesity and underscores the growing body of evidence supporting safe and effective treatment with EndoBarrier,” said Scott Schorer, president and chief executive officer of GI Dynamics. “We look forward to additional clinical data releases from other leading clinicians’ investigator-initiated clinical studies.”

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 the United States (STEP-1); our ability to execute STEP-1 under FDA’s Investigational Device Exemption; our ability to enlist clinical trial sites and enroll patients in accordance with STEP-1; the risk that the FDA stops STEP-1 early as a result of the

Investor Relations
United States:
Janell Shields
+1 (781) 357-3280
investor@gidynamics.com

Boston, United States
Sydney, Australia
14 June 2019 AEST

occurrence of certain safety events or does not approve an expansion of STEP-1; 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 on 1 July 2019; our ability to restructure the terms of the convertible note with Crystal Amber Fund Limited that is due on 1 July 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.

###

Investor Relations
United States:
Janell Shields
+1 (781) 357-3280
investor@gidynamics.com