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GI Dynamics Announces Worldwide EndoBarrier Registry Data for 871 Patients Presented at EASD 2019

BOSTON and SYDNEY — 20 September 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 from the Association of British Clinical Diabetologists (ABCD) Worldwide EndoBarrier Registry evaluating the benefit: risk of EndoBarrier, presented by Katharina Laubner, M.D. of the University of Freiburg. The data was presented at the 55th Annual Meeting of the European Association for the Study of Diabetes (EASD) in Barcelona, Spain on 19 September 2019.

The poster "Duodenal-jejunal Bypass Liner (DJBL) for Treatment of Type 2 Diabetes and Obesity – The Risk: Benefit Ratio from the Worldwide EndoBarrier Registry in 871 Patients," demonstrates the safety and efficacy profile that EndoBarrier provides patients diagnosed with type 2 diabetes and/or obesity. The ABCD[1] Worldwide EndoBarrier Registry, led by Robert Ryder, M.D. of City Hospital in Birmingham, U.K, collected data from 28 centers in eight countries throughout the world.

The first ABCD Worldwide EndoBarrier Registry benefit: risk data was presented at the American Diabetes Association's 78th Scientific Sessions in July 2018 by Ryder. Since then, the registry has more than doubled in the number of patient records, including the addition of the complete data set from the German EndoBarrier Registry[2]. The Worldwide EndoBarrier Registry continues to support a positive benefit: risk profile for patients with type 2 diabetes and/or obesity treated with EndoBarrier.

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[1] Association of British Clinical Diabetologists: https://abcd.care/
[2] EndoBarrier Registry Deutschland: https://ichgcp.net/clinical-trials-registry/NCT02731859

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"In this analysis of the Worldwide EndoBarrier Registry, the data highlights clinically significant reductions in HbA1c (1.2% absolute mean reduction) and weight (13.7kg mean reduction) as well as improvements in associated cardiovascular metrics (systolic BP: 7.4 mmHg reduction, cholesterol: 0.55 mmol/L reduction)," said Laubner. "When considering the overall clinical benefit of EndoBarrier treatment with the acceptable risk profile, the data combines to present a positive case for treatment of patients with type 2 diabetes and obesity."

Benefit

The data show significant reductions in HbA1c, weight, systolic blood pressure (BP) and cholesterol at time of EndoBarrier explant.

Parameter	n	Baseline	Explant	Difference	P-value
Weight (kg)	662	121.6 ± 25.8	107.9 ± 26.4	↓13.7 ± 9.8	<0.001
HbA1c (%)	501	8.2 ± 1.8	7.0 ± 1.2	↓1.2 ± 1.4	<0.001
Systolic Blood Pressure (mmHg)	298	137.9 ± 18.2	130.5 ± 16.8	↓7.4 ± 20.1	<0.001
Cholesterol (mmol/L)	332	4.8 ± 1.2	4.3 ± 1.0	↓0.55 ± 0.98	<0.001

n = patient population

As expected, when comparing outcomes of HbA1c reduction, patients with a higher HbA1c at baseline show greater reductions at explant.

HbA1c Range (%)	n	Baseline, Mean %	Explant, Mean %	Difference, Absolute %	P-value
All HbA1c	501	8.2 ± 1.8	7.0 ± 1.2	↓1.2 ± 1.4	<0.001
All HbA1c ≥ 7	377	8.9 ± 1.5	7.4 ± 1.1	↓1.6 ± 1.5	<0.001
All HbA1c ≥ 8	262	9.6 ± 1.4	7.6 ± 1.1	↓1.9 ± 1.5	<0.001
All HbA1c ≥ 9	143	10.5 ± 1.2	7.8 ± 1.2	↓2.7 ± 1.5	<0.001
All HbA1c ≥ 10	86	11.2 ± 1.0	7.9 ± 1.3	↓3.3 ± 1.5	<0.001

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"All the data submitted from the 28 participating centers will continue to improve our efforts of evaluating the safety and efficacy of EndoBarrier," said Ryder. "It is imperative for us, as clinicians, to push for new and innovative technologies, like EndoBarrier, to provide this patient population with alternative ways to help treat or manage their uncontrolled type 2 diabetes and obesity."

"The Worldwide EndoBarrier Registry demonstrates the consistently positive impact EndoBarrier has from 28 clinical sites in eight countries throughout the world," said Scott Schorer, president and chief executive office of GI Dynamics. "We are extremely grateful for the contributions these clinicians continue to make in support of our efforts to bring EndoBarrier to this patient population."

About GI Dynamics

GI Dynamics®, Inc. (ASX:GID) is the developer of EndoBarrier®, the first endoscopically-delivered medical device 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. EndoBarrier is subject to an Investigational Device Exemption by the FDA in the United States and is entering concurrent pivotal trials in the United States and India. Founded in 2003, GI Dynamics is headquartered in Boston, Massachusetts. For more information please visit.

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.

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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 obtain stockholder approval of the conversion feature of the August 2019 Note and issuance of the August 2019 Warrant, 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 occurrence of certain safety events or does not approve an expansion of STEP-1; our ability to enroll patients in accordance with I-STEP; our ability to secure a CE Mark; our ability to maintain compliance with our obligations under our existing convertible note and warrant agreements executed with Crystal Amber, including our obligations to make payment on the Note that is due on 31 March 2020 and our ability to restructure the terms of the Note with Crystal Amber that is due on 31 March 2020 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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