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First Patient Enrolled in the US STEP-1 Clinical Trial of EndoBarrier at Michigan Medicine

BOSTON and SYDNEY — 28 January 2020 — 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 first patient in the United States (U.S.) STEP-1 clinical trial has been enrolled at Michigan Medicine in Ann Arbor, Michigan.

Michigan Medicine is one of five clinical study sites for the STEP-1 trial; the site is led by principal investigator Allison R. Schulman M.D., M.P.H., assistant professor of gastroenterology and internal medicine.

“We are honored to be the first clinical study site to enroll the first patient into the STEP-1 trial,” said Dr. Schulman. “This groundbreaking trial is the first of its kind to measure the primary endpoint of type 2 diabetes combined with reductions in weight, cardiovascular risk, non-alcoholic fatty liver disease (NAFLD), non-alcoholic steatohepatitis (NASH) and chronic kidney disease (CKD). I am excited to help bring an interventional upper gastrointestinal implant procedure for the treatment of multiple metabolic disorders to this patient population.”

The STEP-1 trial is the randomized (3 EndoBarrier: 1 Control) controlled, double-blinded pivotal trial of EndoBarrier in the U.S. The trial is designed to measure the efficacy and safety of EndoBarrier in conjunction with lifestyle therapy and diabetes medication for the treatment of type 2 diabetes and obesity.

“We are constantly seeking new methodologies to treat our growing type 2 diabetes and obesity patient population,” said Elif A. Oral, M.D., professor of metabolism, endocrinology and diabetes at Michigan Medicine. “EndoBarrier has shown significant promise in previous studies by addressing high hemoglobin A1c levels and weight as

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well as other metabolic syndromes, and we look forward to gathering additional data in the STEP-1 trial."

This is the first of 67 patients whom we expect to be enrolled into Stage 1 of the STEP-1 trial. Regardless of what treatment arm the patient is randomized into, all patients will receive identical diabetes medication monitoring and counseling throughout the 24-month study period. Results from the STEP-1 trial will support the company's pre-market approval application for EndoBarrier to the U.S. Food and Drug Administration (FDA).

The STEP-1 trial's lead principal investigator is Christopher C. Thompson M.D., M.H.E.S. of Brigham and Women's Hospital and Harvard Medical School in Boston, Massachusetts. The five clinical trial sites include Brigham and Women's Hospital, Michigan Medicine, Baylor College of Medicine, Thomas Jefferson University and Surgical Specialists of Louisiana.

"I have been excited about EndoBarrier since its development and have paid close attention to the positive data that has been released through investigator-initiated studies performed outside of the U.S.," said Dr. Thompson. "EndoBarrier is a unique device in that it has been shown to produce a clinically and statistically significant impact on type 2 diabetes and obesity as well as on a host of metabolic comorbidities. It is a treatment option that clearly addresses an unmet need for this disease state."

"In addition to measuring the primary endpoint of reduction in blood sugar at 12 months, this landmark study measures a wide variety of metabolic conditions across a two-year period — the first pivotal trial in the U.S. to do so," said Scott Schorer, president and chief executive officer of GI Dynamics. "We hope to gather evidence to support future research of metabolic disorders and data to support an approval in the U.S. through post-market approval."

The company anticipates full enrollment of the 67 patients by the end of 2020.

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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 conducting 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.

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 the STEP-1 trial; 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 maintain compliance with our obligations under our existing convertible notes 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

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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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