Boston, United States
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13 June 2019 AEST

GI Dynamics Confirms First Two Clinical Study Sites Contracted for US Pivotal Trial of EndoBarrier

BOSTON and SYDNEY — 13 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 the execution of contracts with the first two clinical sites of the STEP-1 (single therapy euglycemic procedure, formally known as GID 18-1) pivotal trial of EndoBarrier (U.S.): the University of Michigan in Ann Arbor, Michigan, and Baylor College of Medicine in Houston, Texas.

The U.S. pivotal trial of EndoBarrier, STEP-1, will begin enrolling patients with type 2 diabetes and obesity during the second half of 2019. The primary endpoint of STEP-1 is reduction in average blood sugar levels (HbA1c) at 12 months of treatment. The pivotal trial will consist of randomized EndoBarrier implant and control arms; both arms will receive identical lifestyle therapy that complies with the most current American Diabetes Association guidelines.

The University of Michigan runs one of the largest hospitals in the state of Michigan and is a premier academic medical center. It has been the site of groundbreaking medical and technological advancements in health care since the medical school first opened in 1850. The University of Michigan's vision is to create the future of health care through discovery and to become the national leader in healthcare, health care reform, biomedical innovation and education.

The University of Michigan's principal investigator, Allison R. Schulman M.D., M.P.H. is an assistant professor of gastroenterology and internal medicine. Dr. Schulman brings significant experience as a gastroenterologist with a focus in bariatric endoscopy and advanced endoscopy. "My team and I are eager to start enrolling patients for the STEP-1 study," said Dr. Schulman. "I hope this study will prove safe and effective with the new protocol that GI Dynamics has developed with the support of their scientific advisors."

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Baylor College of Medicine houses over 75 adult specialty clinics, offering patients specialized care through its extensive range of services. Baylor puts leading innovations, treatments, and therapies into the hands of highly trained physicians and care teams to ensure patients are provided with personalized care.

Baylor College of Medicine's Principle Investigator, Wasif M. Abidi, M.D., Ph.D. is an assistant professor and advanced endoscopist, with significant experience in bariatric endoscopy who brings further expertise as a board-certified specialist in gastroenterology and internal medicine. "I am honored to play such a huge role in the STEP-1 study for GI Dynamics," said Dr. Abidi. "EndoBarrier is a unique and innovative treatment option for type 2 diabetes and obesity that will be very attractive to many patients."

"GI Dynamics has been diligently working to enroll highly qualified clinical sites to ensure patient safety and clinical outcomes are the number one priority with our clinical investigators," said Stephen Linhares, vice president of clinical and regulatory affairs of GI Dynamics. "It is imperative that each clinical site is equipped with the tools and knowledge to help STEP-1 be successful, and we are grateful for the support of the institutions and personnel at the University of Michigan and Baylor College of Medicine."

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.

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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 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.

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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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