Boston, United States
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11 July 2019 AEST

GI Dynamics Announces Lead Clinical Study Site for US Pivotal Trial of EndoBarrier

BOSTON and SYDNEY — 11 July 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 its contract with Brigham and Women's Hospital in Boston, Massachusetts as the lead clinical site of the U.S. pivotal trial of EndoBarrier.

The U.S. pivotal trial of EndoBarrier, STEP-1 (Single Therapy Euglycemic Procedure), formally known as GID 18-1, 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.

Brigham and Women's Hospital (Brigham and Women's) is noted for the quality of its health care professionals who dedicate themselves to patient care while pursuing clinical research and enacting innovation. The hospital is ranked among the nation's 20 Best Hospitals according to the U.S. News & World Report in 2018 and 2019; the hospital is listed among Becker Healthcare's 2019 150 Top Places to Work in Healthcare.

Brigham and Women's principal investigator (PI), Christopher C. Thompson M.D., M.H.E.S., is an associate professor at Harvard Medical School who specializes in gastroenterology, hepatology and endoscopy. He is a board-certified doctor of internal medicine and gastroenterology, who is both the director of endoscopy and director of the bariatric endoscopy fellowship program at Brigham and Women's. Dr. Thompson is the author or co-author of more than 200 publications and has participated in or led numerous clinical trials.

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Dr. Thompson is the study PI for the STEP-1 trial, overseeing all clinical site training, patient care and data collection. “I am honored to lead the STEP-1 trial with other forward-thinking clinical sites,” said Dr. Thompson. “I have been working diligently with GI Dynamics and some of the world’s leading clinicians over the past 3 years to bring this pivotal trial of EndoBarrier to the U.S. It is imperative to find new ways to treat type 2 diabetes and obesity and I believe EndoBarrier will help pave the way.”

“Brigham and Women’s is one of the top treatment facilities in the U.S. and a leader in minimally invasive gastrointestinal procedures,” said Stephen Linhares, vice president of clinical and regulatory affairs of GI Dynamics. “It is an honor to have their outstanding team as our lead clinical site for STEP-1. Dr. Thompson was instrumental in the company’s efforts to achieve FDA approval for Stage-1 of the U.S. pivotal trial of EndoBarrier and we look forward to supporting his work as the PI for our STEP-1 study.”

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.

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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 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 October 2019; our ability to restructure the terms of the convertible note with Crystal Amber Fund Limited that is due on 1 October 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.

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