Boston, United States
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31 July 2019 AEST

GI Dynamics Confirms Surgical Specialists of Louisiana Contracted for US Pivotal Trial of EndoBarrier

BOSTON and SYDNEY — 31 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 Surgical Specialists of Louisiana in Metairie, Louisiana, as a clinical site for the STEP-1 (Single Therapy Euglycemic Procedure) U.S. pivotal trial of EndoBarrier.

The STEP-1 trial will begin enrolling patients who have 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; patients in both arms will receive identical lifestyle therapy that complies with the most current American Diabetes Association guidelines.

Surgical Specialists of Louisiana is a leading private healthcare organization of board-certified surgeons and staff who provide an advanced program for weight loss and wellness. They are dedicated to helping patients achieve healthy lifestyles and have helped more than 10,000 patients achieve their health goals.

Surgical Specialists of Louisiana's principal investigator, Thomas E. Lavin, MD, FACS, FASMBS, is a board-certified surgeon and American College of Surgeons fellow. A well-respected speaker in the field of bariatric surgery, he provides significant experience within the field. "I look forward to participating in the STEP-1 trial in conjunction with the other prestigious clinical sites and health care professionals in the study," said Dr. Lavin. "EndoBarrier is an innovative technology with the potential to serve as a much-needed solution for patients who suffer from type 2 diabetes but who have failed to achieve glycemic control."

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"GI Dynamics has dedicated itself to ensure the quality of its clinical sites and the care with which they conduct themselves in preparation for the clinical trials," said Steve Linhares, vice president of clinical and regulatory affairs of GI Dynamics. "We are working to provide the necessary foundation such that the clinical sites may succeed in the most efficacious and safe manner, and we are grateful for the support of Dr. Lavin and the team at Surgical Specialists of Louisiana."

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 occurrence of certain safety events or does not approve an expansion of STEP-1; our

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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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