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14 February 2019 AEDT

GI Dynamics Announces Institutional Review Board Approval for EndoBarrier Pivotal Trial

BOSTON and SYDNEY — 14 February 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 that it has received Institutional Review Board (IRB) approval to conduct its pivotal trial of EndoBarrier for type 2 diabetes and obesity.

As announced on 13 August 2018, the pivotal trial of EndoBarrier, referred to as the 18-1 study, is a randomized (3:1) controlled double-blinded clinical trial 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 vs. a sham control arm in conjunction with lifestyle therapy and diabetes medication, also for the treatment of type 2 diabetes and obesity. The 18-1 study will occur in two stages. Stage I consists of 50 EndoBarrier patients and approximately 17 control patients and will be completed with the filing of four Data Monitoring Committee (DMC) reports with the US Food and Drug Administration (FDA). Upon review of the four DMC reports by the FDA, the company will apply for approval to conduct Stage II of the trial, which is projected to include the balance of patients to complete the 18-1 study total of 240 patients (180 EndoBarrier and 60 control).

IRB approval is required by the FDA and is an essential step to allow the EndoBarrier pivotal trial to proceed. Western IRB (WIRB) is serving as the company's central IRB. GI Dynamics was notified today that the following EndoBarrier pivotal trial documentation is approved by WIRB: protocol, informed consent form, and investigator's brochure.

"When we announced that the FDA approved our Investigational Device Exemption (IDE) for the pivotal trial of EndoBarrier, the approval was conditional upon IRB approval," said Scott Schorer, president and chief executive officer of GI Dynamics.

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"This IRB approval now satisfies that condition. In parallel, we continue to push forward with the clinical study sites that will be part of the 18-1 study and we anticipate being in a position to announce these clinical sites shortly."

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 (18-1 study); our ability to execute the 18-1 study under FDA's Investigational Device Exemption; our ability to enlist clinical trial sites and enroll patients in accordance with the 18-1 study; the risk that the FDA stops the 18-1 study early as a result of the occurrence of certain safety events or does not approve an expansion of the 18-1 study; 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 in March 2019; our ability to restructure the terms of the convertible note

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with Crystal Amber Fund Limited that is due in March 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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