GI Dynamics, Inc. – ASX Announcement

GI Dynamics Announces Top-Line Results from U.S. Pivotal Clinical Trial of EndoBarrier® Therapy (the ENDO Trial)

GI Dynamics to Hold Conference Call and Webcast at 8:30 a.m. AEDT on 16 March 2016 (5:30 p.m. EDT on 15 March 2016)

LEXINGTON, Massachusetts & SYDNEY, Australia – 15 March 2016 AEDT –
GI Dynamics, Inc. (**ASX: GID**) (the **Company**), a medical device company that provides innovative treatments for type 2 diabetes and obesity, today announced it has received the initial top-line results from its U.S. pivotal clinical trial of EndoBarrier Therapy for glycemic improvement in inadequately controlled, obese, type 2 diabetic subjects on oral anti-diabetic agents (the **ENDO Trial**).

In July 2015, the Company terminated the ENDO Trial early due to seven cases of hepatic abscess, a bacterial infection of the liver, a number of cases that was greater than expected. Because of the early termination, only 325 of the planned 500 subjects were randomized into the trial. The smaller final sample size provides less statistical power for analyses than originally planned. Nonetheless, the pre-specified analysis methods were used to obtain the results of the ENDO Trial discussed below, based on final data collected and locked as of 3 March 2016.

Based on the initial analysis of the final dataset, the ENDO Trial demonstrated efficacy of EndoBarrier Therapy for the treatment of type 2 diabetes with an average reduction of hemoglobin A1c (**HbA1c**) from baseline to 12 months that was 0.71% greater with the device than with sham intervention. The effectiveness of EndoBarrier Therapy, however, did not meet the protocol-specified Primary Efficacy Endpoint criterion, a statistical test that demonstrates a greater than 96.5% probability that the change in HbA1c was at least 0.4% greater with EndoBarrier Therapy than with sham control. The pre-specified probability criterion was 96.5%, compared with the result of 92.8%. These results are nonetheless encouraging, given that (1) the trial only enrolled two-thirds of the intended subjects; and (2) because of early suspension of the trial, data for nearly one-third of the enrolled and randomized subjects were not available for the protocol-specified primary efficacy analysis.

With respect to safety, EndoBarrier Therapy did not meet the protocol-specified Primary Safety Endpoint, defined by device-related serious adverse events (**SAEs**) requiring early device removal as adjudicated by an independent Clinical Events Committee. Device-related SAEs requiring removal occurred in 11.7% of subjects. However, it did not meet the protocol-specified Primary Safety Endpoint criterion, a statistical test to demonstrate the incidence of primary safety events with EndoBarrier Therapy was less than 15%. The pre-specified probability criterion was 96.5%, compared with the result of 90.5%. This safety failure was largely due to the excess number of hepatic abscess that occurred in subjects implanted with the device. Notably, no additional cases of hepatic abscess have been identified or reported since the ENDO Trial was terminated in July 2015. All subjects with previous hepatic abscess have had complete resolution with no known clinical sequelae reported.

The Company plans to submit the final report of the ENDO Trial to the Food and Drug Administration (**FDA**) in April 2016, and anticipates peer-reviewed publications and presentations at scientific conferences to provide the public with a more detailed analysis of the trial data.

Although the ENDO Trial did not achieve its primary safety endpoint, evaluation of the safety data has revealed an opportunity to improve the clinical algorithm for the use of EndoBarrier Therapy. This optimized treatment algorithm is specifically designed to reduce the incidence of hepatic abscess and improve overall safety without compromising device efficacy, resulting in an improved benefit:risk profile. The revised algorithm was developed and approved by an advisory board consisting of 14 experienced EndoBarrier users, representing the fields of endocrinology, diabetology, gastroenterology, and bariatric surgery.

Based on the clinically-relevant efficacy demonstrated in the ENDO Trial, the Company plans to continue discussions with the FDA for the purpose of seeking approval of an investigational device exemption to conduct a new U.S. clinical trial to determine the efficacy and safety of EndoBarrier using the revised clinical treatment algorithm.

The Company will hold a conference call to update investors regarding the ENDO Trial, secondary outcomes, and future plans and objectives for the Company. Jack Meyer, Chairman of the Board of Directors, will host the call.

8:30 a.m. AEDT on 16 March 2016 (5:30 p.m. EDT on 15 March 2016)

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Accessing the Conference Call via Webcast:

A live webcast of the call will be available on the GI Dynamics website at investor.gidynamics.com. The webcast can be directly accessed at: http://edge.media-server.com/m/p/b9yio5wf.

Accessing the Conference Call via Telephone:

For those preferring to listen by telephone, please dial in five minutes prior to the start of the call and provide the passcode **69477133**. Regional dial-in numbers are as follows:

- **United States** callers please dial toll free 1 (877) 280-1758
- **Australia** callers please dial toll free 1 800 005 989
- **International** callers please dial 1 678 562 4233

Replay archive:

The webcast will be archived for 30 days following the call on the GI Dynamics website at investor.gidynamics.com.

About GI Dynamics

GI Dynamics, Inc. (ASX: GID) is the developer of EndoBarrier®, the first endoscopically-delivered device therapy approved for the treatment of obese type 2 diabetes with BMI ≥ 30 kg/m^2, or obese patients with BMI ≥ 30 kg/m^2 with ≥ 1 comorbidities, or obese patients with BMI >35 kg/m^2. The liner is indicated for a maximum implant duration of 12 months. EndoBarrier is approved and commercially available in multiple countries outside the U.S. EndoBarrier is not approved for sale in the U.S. and is limited by federal law to investigational use only in the United States. Founded in 2003, GI Dynamics is headquartered in Lexington, Massachusetts. For more information, please visit www.gidynamics.com.

Forward-Looking Statements

This announcement contains forward-looking statements concerning: our development and commercialization plans; our potential revenues and revenue growth, costs, excess inventory, profitability and financial performance; our ability to obtain reimbursement for our products; our clinical trials, and associated regulatory submissions and approvals; the number and location of commercial centres offering the EndoBarrier; and our intellectual property position. These forward-looking statements are based on the current estimates and expectations of future events by the management of GI Dynamics, Inc. as of the date of this announcement and are subject to a number of 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 the consequences of terminating the ENDO Trial and the possibility that future clinical trials will not be successful or confirm earlier results; risks associated with obtaining funding from third parties; risks relating to 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, and the timing and extent of third-party reimbursement; risks associated with commercial product sales, including product performance; competition; risks related to market acceptance of products; intellectual property risks; risks related to excess inventory; risks related to assumptions regarding the size of the available market, 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, you 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, future events or otherwise, unless required by law.

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