GI Dynamics, Inc. - ASX Announcement

GI Dynamics Announces Launch of EndoBarrier® Therapy Clinical Utility Study in France

LEXINGTON, Massachusetts & SYDNEY, Australia – 30 July 2014 – GI Dynamics, Inc. (ASX: GID) today announced that the first patients have been enrolled in a large, randomized, multi-center, clinical utility study of EndoBarrier® Therapy (ENDOMETAB), sponsored by the French Ministry of Social Affairs and Health. EndoBarrier Therapy is the world's first endoscopically-delivered device therapy approved for the treatment of type 2 diabetes and/or obesity.

The study, which is being conducted at 10 leading academic centers throughout France, is designed to evaluate the impact and cost of 12 months of treatment with EndoBarrier Therapy compared to 12 months of conventional treatment (dietary counseling, physical activity and lifestyle changes). Approximately 174 patients suffering from obesity, both with and without diabetes, are expected to enroll. ENDOMETAB is part of the soutien aux techniques innovantes coûteuses (STIC) program, which provides government funding for innovative medical technologies that have an established clinical profile, but where additional information concerning clinical utility and potential reimbursement status is sought. The trial is expected to complete in 2016.

"Obesity and diabetes are serious disorders that affect millions of people in France for whom the best available treatments are still suboptimal," said Professor François Pattou, professor of general surgery and head of the department of general and endocrine surgery at University Hospital Lille, and a principal investigator in the ENDOMETAB study. "We need better and more effective treatments that can improve blood sugar and promote weight loss at the same time. The results we have seen patients achieve with EndoBarrier Therapy thus far have been very encouraging and we are pleased to be conducting this important study."

Stuart A. Randle, president and CEO of GI Dynamics, added, "The enrollment of the first patient in this government-sponsored study represents a step toward securing reimbursement in France, and is part of our long-term strategy to make EndoBarrier Therapy more broadly available. Additional options are needed for people suffering from diabetes and obesity, and we are hopeful that this study will help to clearly demonstrate both the clinical and economic utility of EndoBarrier Therapy in the management of these conditions."

About GI Dynamics

GI Dynamics, Inc. (ASX: GID) is the developer of EndoBarrier®, the first endoscopically-delivered device therapy approved for the treatment of type 2 diabetes and/or obesity. 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. GI Dynamics is conducting a pivotal clinical trial of EndoBarrier in the U.S. for the treatment of patients who have uncontrolled type 2 diabetes and are obese. 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, costs, 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 possibility that 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, results of clinical trials, the timing of regulatory submissions, the timing and receipt of regulatory approvals, the timing and amount of other expenses; execution risks; competition; risks related to market acceptance of products; intellectual property risks; and assumptions regarding the size of the available market, benefits of our products, product pricing, timing of product launches, future financial results and other factors. 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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