GI Dynamics Releases EndoBarrier Re-Implantation Data from German Diabetes Congress

Boston, United States
Sydney, Australia
6 June 2017 AEST

BOSTON and HAMBURG, 6 June 2017—GI Dynamics® Inc. (ASX:GID), a medical device company that has commercialized EndoBarrier® in Europe, the Middle East, and South America for patients with type 2 diabetes and obesity brought forward data from an investigator-initiated study presented at the German Diabetes Congress 2017 in Hamburg, Germany. Initial data was introduced that examined the safety and efficacy of EndoBarrier re-implantation for the treatment of patients with type 2 diabetes and obesity.

The observational study titled "Is Re-Implantation of the Duodenal-Jejunal Bypass Liner Viable?" explored whether it is technically feasible to re-implant EndoBarrier in patients who previously had the device implanted and explanted, as well as whether the re-implantation would achieve similar weight and metabolic effects as on patients who had received prior EndoBarrier implantation.

Five patients participated in this study. Each patient completed an initial course of EndoBarrier treatment for a twelve month period. The device was explanted and the patients were monitored for 4 months. A second EndoBarrier was then implanted for a twelve month course of treatment and subsequently removed.

	Implant 1 / (Baseline)	Explant 1	Rest Period	Implant 2	Explant 2
	12 months -->		4 months	12 months -->	
HbA1c, %	**9.1%**	**6.7%**		**7.8%**	**7.1%**
Reduction, absolute %		2.4%			0.7%
				from baseline:	*2.0%*
Total Body Weight, kg	**115.8**	**95.0**		**97.3**	**91.1**
Reduction, kg		20.8			6.2
				from baseline:	*24.7*
BMI (kg/m^2)	**33.9**				**32.5**
Insulin, iU/day	**60**	**19**		**33**	**20**
Reduction, iU/day		41			13
				from baseline:	*40*

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“Although small, this study provided important information regarding serial usage of EndoBarrier,” said Jurgen Stein, MD, the Primary Investigator of this study. “Re-implantation and re-explantation of the EndoBarrier device were performed on all five study subjects without any complications, and the early clinical data is promising. In addition, there was a significant reduction in insulin.”

“The study shows early indication of efficacy to support multiple treatments utilizing EndoBarrier. Especially encouraging is the reduction of blood sugar and weight combined with concurrent reduction in insulin,” said Scott Schorer, president and CEO of GI Dynamics. “We appreciate Dr. Stein’s efforts to conduct a study that adds such interesting insights into the growing body of evidence proving EndoBarrier safety and efficacy.”

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 obesity. EndoBarrier is approved and commercially available in multiple countries outside the United States. EndoBarrier is not approved for sale in the United States and is limited by federal law to investigational use only in the United States. Founded in 2003, GI Dynamics is headquartered in Boston, Massachusetts. For more information, please visit www.gidynamics.com.

Forward-Looking Statements

This announcement contains forward-looking statements concerning the potential for EndoBarrier as an important treatment option for patients with type 2 diabetes and obesity. These forward-looking 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

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uncertainties include but are not limited to, risks associated with obtaining funding from third parties; the consequences of stopping the ENDO trial and 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; risks associated with commercial product sales, including product performance, competition, market acceptance of products, intellectual-property risk; risks related to excess inventory; and 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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