



Press Release

Boston, Massachusetts
United States
Sydney, Australia
November 22, 2016 AEDT

EndoBarrier® Makes Advancement Toward German Reimbursement

GI Dynamics®, Inc. (ASX: GID), a medical technology company that has developed an innovative device to improve outcomes for patients with type 2 diabetes and obesity, continues to make progress toward full reimbursement in Germany. Germany is typically the second largest market for medical technology in the world and is a high priority country for GI Dynamics.

German hospitals have made significant legal progress against resistance to EndoBarrier® reimbursement. Recent court decisions reinforce the assertion that payers must support NUB¹ new technology payments for EndoBarrier procedures.

An arbitration court ruling had denied NUB payments for Frankfurt Sachsenhausen Hospital based upon the argument that the available clinical evidence did not support the treatment efficacy of EndoBarrier. The state government of Hessen rejected this court ruling and confirmed that the [Consensus Paper](#)² of three German medical societies was sufficient evidence to support NUB payment. This position paper outlines the efficacy of EndoBarrier in treating type 2 diabetes and obesity. The conclusions of the paper were publicly reinforced in a [Statement](#) by the German Diabetes Society in 2015.

“These legal victories underscore the strong clinical and healthcare system support for EndoBarrier. We appreciate that the hospitals and court system are willing to work through the facts and support the correct administration of NUB new technology payments,” said Scott Schorer, President and CEO of GI Dynamics.

“Multiple hospital systems have taken the time-consuming action of advocating strongly for EndoBarrier reimbursement. These legal actions, together with strong combined consensus support from the German Diabetes Association

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¹ “NUB”: Neue Untersuchungs- und Behandlungsmethoden”, in German, or: New Diagnostic and Treatment Methods. The correct wording translated from German: “additional payments for new diagnostic and treatment methods (NUB)”.

² Position Paper of Scientific Societies for Recommended Usage of Endoscopic Biliiodigestive Diversion in Germany – German Diabetes Association (DDG) / German Society for General and Visceral Surgery (DGAV) / German Society for Digestive and Metabolic Diseases (DGVS)



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(“DDG”), the German Society for General and Visceral Surgery (“DGAV”), and the German Society for Digestive and Metabolic Diseases (“DGVS”) underscore the significance of EndoBarrier as a unique treatment option for patients suffering from type 2 diabetes and obesity,” said Schorer.

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 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 centers 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, and 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

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excess inventory; and 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 US 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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