GI Dynamics Announces EndoBarrier CE Mark Suspension

Boston, United States
Sydney, Australia
18 May 2017 AEST

BOSTON and SYDNEY — 18 May 2017 — GI Dynamics®, Inc. (ASX:GID) today announced that it received notification from its notified body SGS United Kingdom Limited (SGS) that the CE Mark for its EndoBarrier® system has been suspended pending closure of nonconformances related to its quality management system required under ISO 13485:2003 and 93/42/EEC.

“This action does not call the safety and efficacy of EndoBarrier into question and this action does not constitute a recall,” said Scott Schorer, CEO and president. “We are working swiftly to address issues within our quality management system that were detailed in a corrective action report from SGS; we will have these nonconformances resolved and have our CE Mark reinstated as quickly as possible.”

Since the new management team at GI Dynamics assumed leadership last spring, the company has been working diligently to address these and other issues. The company has shipped what it believes will be sufficient inventory to its customers to ensure uninterrupted service during the suspension. In addition, all implanted patients may continue treatment subject to normal ongoing evaluation and monitoring by their healthcare professional.

Specific plans and actions have been initiated to address the nonconformances identified by SGS.

“We hired a chief compliance officer with experience in these matters as well as quality and regulatory experts to help us address the issues while maintaining compliant surveillance and vigilance,” Schorer said. “We have made significant progress over the past year and are focused on continuous improvement to the quality management system.”

“We are committed to ensuring EndoBarrier is available for our patients and clinicians.”

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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 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 expectations regarding the effect of the CE mark suspension, our ability to resolve nonconformance issues to the satisfaction of our notified body, and the timing of any reinstatement of our CE mark. 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 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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