GI Dynamics Receives CE Certificate of Conformity Withdrawal Notice for EndoBarrier

Boston, United States
Sydney, Australia
13 November 2017 AEDT

BOSTON and SYDNEY — 13 November 2017 — GI Dynamics®, Inc. (ASX:GID), a medical device company that has commercialized EndoBarrier® in Europe, the Middle East and South America has received notification from its notified body SGS United Kingdom, Limited (SGS) that SGS will withdraw the CE Certificate of Conformity for EndoBarrier effective 12 November 2017.

As previously announced, on 17 May 2017 the company received notification from SGS that the EndoBarrier CE Certificate of Conformity was being suspended pending resolution of nonconformances related to ISO 13485 compliance. The company has been working diligently to address the issues raised by SGS. On Saturday 11 November 2017 (AEDT) the company received notification that SGS will withdraw the CE Certificate of Conformity issued to the company for EndoBarrier effective 12 November 2017.

The company is evaluating its options including grounds for appeal of the decision, consulting with its advisors and has initiated communications with SGS to clarify certain procedural and substantive matters relating to the notice.

Withdrawal of the CE Certificate of Conformity means that the company will not be able to affix the CE Mark and sell EndoBarrier in European Union countries until another Certificate of Conformity is issued by SGS or another notified body or any appeal is successful.

The company will provide further updates as information becomes available.

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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.

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Forward-Looking Statements

This announcement contains forward-looking statements. 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 and maintaining regulatory approvals required to market and sell our products; 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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