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EndoBarrier Therapy wins BioSpectrum product award

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GI Dynamics' EndoBarrier Therapy wins BioSpectrum Asia Pacific Product of the Year 2013 award



Diabetes has emerged as a major concern in Asia Pacific and companies are making a beeline to develop treatments for it. ASX-listed GI Dynamics has developed a novel treatment, called EndoBarrier Therapy, that does not rely on either medication or surgery to help patients regain control of type 2 diabetes and obesity.

"The EndoBarrier device was first implanted in a human subject in 2005 and has evolved steadily since then. Today, the number of patients treated with EndoBarrier Therapy exceeds 800 and we continue our research and development efforts to enhance the product and treatment program, and to explore additional uses of the technology," says Mr Stuart A Randle, president and CEO, GI Dynamics.

Clinical trials and commercial applications have shown that many patients, while receiving EndoBarrier Therapy, have been able to decrease their dosage of oral anti-diabetes medications.

The effects of EndoBarrier Therapy on glucose control are rapid. The EndoBarrier medical device may be implanted for up to 12 months and has shown benefits in three-month, six-month and 12-month studies. "Our current data demonstrate that 87 percent of the patients are able to reach healthy blood sugar levels and lose an average 18 percent of their total body weight in nine months. Initial studies have demonstrated that EndoBarrier Therapy has sustained benefits on glycemic control and weight loss in up to six months post-explant," says Mr Randle.

Till date, the company has raised $156 million in capital, which has been used toward employee costs, company operations, research and development, ongoing clinical trials, and sales and marketing of the product. The product is commercially available in Australia, Chile and several European countries including the UK, Germany, Austria and the Netherlands.

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In October 2012, the company received full approval from the US Food and Drug Administration to commence a pivotal clinical trial. In January this year, the company initiated the trial with 500 people living with uncontrolled type 2 diabetes and obesity in 25 sites in the US.

The price of the therapy varies in different markets. In addition to private or self-paying patients, GI Dynamics is utilizing a mixture of reimbursement mechanisms across markets, including pursuing national reimbursement, regional insurances, local institutional-level funding and more for its pricing model. "To expand our patient population and increase sales, our goal is to

obtain reimbursement for our product from local and national health authorities in our target markets," explains Mr Randle.

"We are currently gathering the necessary clinical and economic data that will support our application for reimbursement in key countries. Our reimbursement strategy will involve applying for reimbursement codes, lobbying obesity and diabetes societies and establishing pricing and cost models. Several of these reimbursement activities are underway in the UK, Netherlands, Austria and Germany at the local or national level."

GI Dynamics has a committed global development program for EndoBarrier Therapy. "Our strategy in 2013 is to focus on maximizing the success and market penetration of our existing centers, while also commencing sales in a select number of new markets," says Mr Randle The company is currently focused on the transition from its successful clinical trial experience to broader commercialization.