Reshaping the Obesity Treatment Paradigm

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LONDON, UK (GlobalData), 18 April 2012 - **Obesity** is a major issue in the developed world, affecting more than **500 million adults** over the age of 20 according to the World Health Organization. Obesity is associated with conditions such as metabolic syndrome, diabetes, ischemic heart disease and certain cancers, and is responsible for an estimated

2.8 million deaths each year

. Current treatment methods such as lifestyle changes through diet and exercise have only moderate success due to low adherence to regimens and the difficulty of attaining positive, encouraging results. New drugs targeting obesity such as Vivus' Qnexa, Arena's Lorqess, and Orexigen's Contrave are still hung up in the approval process, and their long term use and safety profiles are still being questioned.

There are also the much more invasive interventions aimed at controlling obesity, such as gastric bypass surgery, gastric sleeve surgery or bilopancreatic diversion with duodenal switch. These invasive treatments are irreversible, and require patients to undergo serious surgical procedures which permanently change their physiology. Many serious side effects and complications are associated with these procedures, including death.

With obesity at epidemic proportions and current treatments only mildly effective or invasive, there is a need for medical device companies to design innovative, less invasive medical treatments to combat the disease. One medical device company attempting to capitalize on this market is Massachusetts based GI Dynamics, which currently markets its revolutionary EndoBarrier for use in Europe, Chile and Australia. The EndoBarrier works similarly to gastric bypass by allowing partially digested food to bypass the duodenum and proximal jejunum, delaying a patient's digestion. It works by creating a physical barrier between the wall of the intestine and the ingested food, slowing digestion and intervening with the body's metabolic functions, resulting in improved glycemic control and weight loss. The EndoBarrier is currently approved for a 12 month treatment as a non-surgical option to treat type 2 diabetes and obesity.

A major advantage for the EndoBarrier is its strong safety profile. The device is implanted in an outpatient setting under conscious sedation using endoscopy, and does not require surgical cutting or invasive surgery. This is preferable to current treatment methods: even the popular LAP-BAND system from Allergan used for weight loss is implanted laproscopically under general anesthesia. The EndoBarrier procedure usually takes less than 30 minutes, and after 12 months of treatment the EndoBarrier is removed without altering the patient's digestive

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system.

In addition to its safety profile, the EndoBarrier has been shown to be effective. In a study conducted over a 12 month period, patients implanted with the EndoBarrier showed a 20% decrease in total body weight and a significant reduction in HbA1c (%). HbA1c is used to monitor plasma glucose concentration in patients with diabetes, and a decrease is indicative of improved glucose management. The promising results from this study have enabled GI Dynamics to receive an investigational device exemption approval from the FDA to conduct a pilot study in the US. In addition to the green light from the FDA, GI Dynamics has received attention from medical device goliaths Medtronic and Johnson & Johnson, who make up some of their corporate shareholders.

While GI Dynamics is attempting to claim a large share of the obesity market, competition looks to be heating up. Other devices including Satiety's TOGA System, IntraPace's Abiliti System and Endosphere's SatiSphere, which are all seeking a piece of the pie.

The Society of Actuaries estimated that the total cost of medical care for patients with obesity in the US added up to more than \$270 billion in 2011 alone. With healthcare systems across the globe searching for ways to save money, GlobalData believes GI Dynamics offers a unique value proposition, as the EndoBarrier provides clear benefits over other therapies in the fight against obesity and diabetes. Surgery using the LAP-BAND currently costs between \$15,000-\$25,000, while gastric bypass can run as high as \$40,000. The high prices for these surgeries are not only a barrier to treatment but a drain on the healthcare system. The EndoBarrier device is currently priced at around \$4,400 in the UK, and because the device is non-invasive and quickly implanted the total procedure costs should be lower than the more invasive options. For new devices to be successful in the marketplace they need to not only be effective in treating the disease, but must also prove that they can provide cost savings to the overall healthcare system. As long as the US pilot study attains the anticipated results, GlobalData believes that the EndoBarrier has the potential to meet both these criteria and change the standard of care for patients battling obesity, metabolic syndrome, and type 2 diabetes.

ABOUT GLOBALDATA

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