Apollo Endosurgery Receives FDA Breakthrough Device Designation for the Orbera(R) Intragastric Balloon for Treatment of Patients with NASH

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AUSTIN, TX / ACCESSWIRE / March 1, 2021 / Apollo Endosurgery, Inc. ("Apollo") (NASDAQ:APEN), a global leader in minimally invasive medical devices for gastrointestinal and bariatric procedures, announced today that it has received a Breakthrough Device Designation from the U.S. Food and Drug Administration for the Orbera® Intragastric Balloon, specifically for the indication for use in treating patients with BMI between 30-40 kg/m^2 with noncirrhotic nonalcoholic steatohepatitis (NASH) with liver fibrosis. The FDA Breakthrough Device Program is intended to help patients receive more timely access to breakthrough technologies that have the potential to provide more effective treatment or diagnosis for life-threatening or irreversibly debilitating diseases or conditions.

Non-alcoholic steatohepatitis (NASH) is a severe form of fatty liver disease, which is associated with liver inflammation and can progress to cirrhosis and liver failure. Patients with NASH have an increased risk of morbidity and mortality from liver-related causes, and NASH is one of the top three conditions leading to liver transplant.[1] The adult US NASH population having a BMI between 30-40 kg/m^2 is approximately 10 million, and while there are currently no FDA approved treatments for NASH, weight loss is the recommended treatment and essential for meaningful improvement in NASH. Current treatment guidelines aim for 7-10% Total Body Weight Loss (TBWL). With this degree of weight loss, NASH histologic characteristics improve in a significant percentage of patients, with resolution of liver inflammation, fat leaving the liver, and regression of fibrosis over time. However, patients typically fail to achieve these requisite levels of weight loss using lifestyle management programs alone.

"Orbera has consistently shown, both in the pivotal study and the post-market approval study, the ability to help patients lose an average of 7-10% TBWL over 6-12 months, which is significantly greater than lifestyle modification alone," said Dr. Christopher Gostout, Apollo Endosurgery, Chief Medical Officer. "The literature and the Mayo IDE study suggest that these levels of weight loss can have a positive effect in resolving or delaying the progression of NASH. With Breakthrough Designation, we will be able to further build the body of clinical evidence and seek label expansion for the use of Orbera for patients with NASH."

The Mayo Clinic IDE-approved (G160077) study was explicitly designed to evaluate the effects of Orbera placement on metabolic and histologic features of NASH, including NAS (indicative of resolution of fat and inflammation in the liver) and fibrosis score. There was notable improvement in these NASH outcome measures when Orbera was removed after 6 months. Specifically:

- Non-Alcoholic Fatty Liver Disease Activity Score (NAS) improved in 18/20 patients (90%), and 16/20 (80%) of patients decreasing by ≥2 points.
- 15% had histologic regression of fibrosis (scarring), and magnetic resonance elastography (MRE) - detected fibrosis improved in 50% (10/20) patients.[2]

While Orbera has been FDA approved since 2015 for weight loss, the grant of Breakthrough Device Designation is an important step forward for potentially addressing a significant unmet need of improving the health of NASH patients.

1 https://www.niddk.nih.gov/health-information/liver-disease/nafld-nash

2 Bazerbachi F, Vargas EJ, Rizk M, Masselli DB, Mounajjed T, Venkatesh SK, Watt KD, Port JD, Basu R, Acosta A, Hanouneh I, Gara N, Shah M, Mundi M, Clark M, Grothe K, Storm AC, Levy MJ, Abu Dayyeh BK; Clin Gastroenterol Hepatol 2020 Apr 30

About Orbera

Orbera is an incision-less, non-surgical weight loss solution designed for adult patients suffering from obesity, who are not appropriate for or considering surgery, but for whom diet, and exercise or pharmaceutical interventions have not worked.

In a non-surgical (endoscopic) procedure, the thin and deflated Orbera balloon is placed into the stomach. It is then filled with saline until it's about the size of a grapefruit. The procedure typically takes about 20 minutes and the patient can generally go home a few hours later. After up to 6 months, through another non-surgical procedure, the Orbera balloon is deflated and then removed.

Once the balloon is in place, the patient works with their physician and their staff in a formal lifestyle modification program to meet their long-term weight loss goals. Coaching takes place over 12 months while the balloon is in place. The program is designed to help the patient develop sustainable, healthy habits that will help keep weight off over time.

For additional information regarding Orbera, please visit http://www.orbera.com and for full safety information please visit http://apolloendo.com/patient-labeling-and-dfus/#

About Apollo Endosurgery, Inc.

Apollo Endosurgery, Inc. is a medical technology company focused on the development of next-generation, less invasive devices to advance gastrointestinal therapeutic endoscopy designed to treat a variety of gastrointestinal conditions including closure of gastrointestinal defects, managing gastrointestinal complications and the treatment of obesity. Apollo's device-based therapies are an alternative to invasive surgical procedures, thus lowering complication rates and reducing total healthcare costs. Apollo's products are offered in over 75 countries today and include the OverStitch™ Endoscopic Suturing System, the OverStitch Sx™ Endoscopic Suturing System, X-Tack™ Endoscopic HeliX Tacking System and the Orbera Intragastric Balloon.

Apollo's common stock is traded on NASDAQ Global Market under the symbol "APEN". For more information regarding Apollo Endosurgery, go to: www.apolloendo.com.

Cautionary Note on Forward-Looking Statements

Certain statements in this press release are forward-looking statements that are subject to risks and uncertainties that could cause results to be materially different than expectations. In addition, there is uncertainty about the continued spread of the COVID-19 virus and the impact it may have on the Company's operations, the demand for the Company's products, the Company's liquidity position, global supply chains and economic activity in general. Important factors that could cause actual results to differ materially include: reports of adverse events related to our products, outcomes of clinical studies, developments in medical technology, regulatory approvals and extensive regulatory oversight by the FDA or other regulatory bodies, unfavorable media coverage related to our products or related procedures, reimbursement decisions by private or government payors, physician adoption and recommendations of procedures utilizing our products as well as other factors detailed in Apollo's periodic reports filed with the Securities and Exchange Commission, or SEC, including its Form 10-K for the year ended December 31, 2020. Copies of reports filed with the SEC are posted on Apollo's website and are available from Apollo without charge. These forward-looking statements are not guarantees of future performance and speak only as of the date hereof, and, except as required by law, Apollo disclaims any obligation to update these forward-looking statements to reflect future events or circumstances.

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