Apollo Endosurgery, Inc. Announces the Presentation of ORBERA™ Intragastric Balloon US Pivotal Trial Results at Digestive Disease Week® 2015 Conference (DDW)

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AUSTIN, Texas--(BUSINESS WIRE)--Apollo Endosurgery, Inc., a leader in minimally invasive endoscopic surgical products for bariatric and gastrointestinal procedures, today announced the presentation of results from the ORBERA™ Pivotal Trial at this year’s Digestive Disease Week (DDW) conference. The study showed that ORBERA™ Intragastric Balloon users lost significantly more weight than the control group, leading to significant improvement in weight related quality of life and improved eating behaviors.

“At the completion of the study, it was clear that the ORBERA™ Intragastric Balloon produced significant weight loss and quality of life benefits, when compared to the study’s control group,” said Dr. Barham Abu Dayyeh, Gastroenterologist and Advanced Endoscopist at The Mayo Clinic. “The results of this study prove that ORBERA™ can be an outstanding tool to aide weight loss and support sustainable, healthy habits, even after it has been removed.”

In the US pivotal ORBERA™ clinical trial, a multicenter, prospective, randomized, non-blinded comparative study, obese patients with a BMI between 30 and 40 were randomized to treatment or control in a 1:1 ratio. The treatment group underwent placement of the ORBERA™ balloon followed by removal after 6 months. They concurrently participated in a 12-month behavioral modification program. The control group participated in the 12-month behavioral modification program alone. For patients in the treatment group, the device was removed at month 6, with regular office visits continuing through 1 year.

A total of 125 patients were randomized to the treatment group and 130 patients were randomized to the control group. More than three-fourths (78.4 percent, 98/125) of the treatment group and 71.5 percent (93/130) of the control group completed the full study at Week 52.

Detailed findings from the trial include:

- At month six, the ORBERA™ group achieved a mean of 40 percent Excess Weight Loss (EWL), with 72 percent of ORBERA™-treated patients achieving at least 25 percent EWL
- Mean Total Body Weight Loss (TBWL) at six months was 10.54 percent for the treatment group compared to 4.71 percent TBWL for the control group.
- The ORBERA™ group lost over twice as much weight as the control group at six months.
- The ORBERA™ group also lost significantly more weight than the control group over the course of the study, and was able to maintain significant weight loss through month 12, six months after removal of the device.

The ORBERA™ Pivotal Trial results were presented at the AGA/ASGE Joint Presidential Plenary Sessions by Dr. Barham Abu Dayyeh. The DDW session was titled “A Randomized, Multi-Center Study to Evaluate the Safety and Effectiveness of an Intragastric Balloon as an Adjunct to a Behavioral Modification Program, in Comparison with a Behavioral Modification Program Alone in the Weight Management of Obese Subjects.” Apollo Endosurgery is exhibiting at booth 1905.

About Digestive Disease Week®

Digestive Disease Week® (DDW) is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW takes place May 16-19, 2015, at the Walter E. Washington Convention Center, Washington, DC. The meeting showcases more than 5,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. More information can be found at www.ddw.org[3].

About Apollo Endosurgery, Inc.

Apollo Endosurgery, Inc. is a leader in minimally invasive endoscopic surgical products for bariatric and gastrointestinal procedures. Apollo Endosurgery was cofounded with the Apollo Group, a unique collaboration of physicians from the Mayo Clinic, Johns Hopkins University, Medical University of South Carolina, the University of Texas Medical Branch and the Chinese University of Hong Kong. This collaboration developed a broad portfolio of patents in the field of endoscopic surgery that became the foundation of Apollo Endosurgery. For more information regarding Apollo Endosurgery, go to: www.apolloendo.com[4].

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