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Data Evaluating Safety and Efficacy of the Halo³⁶⁰ System in Treating Barrett's Esophagus Presented at DDW

CHICAGO, ILL.—Booth #1256—Digestive Disease Week—May XX, 2005— BARRX Medical, Inc. today announced the results of four studies evaluating safety, dosage response and efficacy of treating Barrett's esophagus with the Halo³⁶⁰ System. The study results, presented at to Digestive Disease Week[®] (DDW[®]), May 14-19, 2005, clearly demonstrate the benefits of the Halo³⁶⁰ System for the treatment of Barrett's esophagus, a precancerous condition affecting the lining of the esophagus.

Virender K. Sharma, M.D. of the Mayo Clinic in Scottsdale, Ariz., presented data from the Ablation of Intestinal Metaplasia (AIM-I) multi-center, prospective, randomized trial of 31 patients examining the safety, feasibility, tolerability and dose response in ablating short segment Barrett's esophagus. After the procedure, patients underwent endoscopy at one, three, six and 12 months to determine the amount of Barrett's removed. At six months, 75 percent of patients from one treatment group were cured of Barrett's tissue. The authors conclude that the procedure is effective in the circumferential destruction of Barrett's esophagus without significant complications, specifically no findings of stricture formation or buried glands.

David E. Fleischer, M.D., also of the Mayo Clinic in Scottsdale, Ariz., presented the results of the AIM-II multi-center, prospective trial of 70 patients evaluating the safety, feasibility and tolerability of ablating Barrett's esophagus with the Halo³⁶⁰ System. At six months follow up, the majority of patients had no evidence of Barrett's tissue on biopsy. Those patients with persistent disease had experienced a significant reduction in their Barrett's and remained eligible for retreatment. Follow-up tests revealed no strictures or buried glands. The authors conclude that the safe removal of Barrett's esophagus in a single treatment is achievable.

In another paper evaluating patients with low-grade dysplasia, a more advanced stage of Barrett's esophagus, Dr. Virender Sharma reported an 80 percent patient response rate after just one treatment at a slightly higher energy dose than that applied in the AIM trials. After a second treatment was applied in patients with persistent low grade dysplasia, the cure rate for low-grade dysplasia at the six month follow-up increased to 100 percent. These data suggest that the Halo³⁶⁰ System can safely and effectively eliminate low-grade dysplasia in patients with Barrett's esophagus.

C. Daniel Smith, M.D. of Emory University School of Medicine, in Atlanta, Ga., presented a study evaluating the optimal treatment parameters for the ablation of Barrett's esophagus with high-grade dysplasia. This study found that the complete ablation of esophageal high-grade dysplasia is possible without causing injury to the healthy underlying tissue.

"The clinical data presented at Digestive Disease Week demonstrate that the Halo³⁶⁰ System can be used to safely and effectively treat Barrett's esophagus," said David S. Utley, M.D., chief medical officer, BÂRRX Medical, Inc. "Upon follow up, the majority of patients treated with the Halo³⁶⁰ System were free of Barrett's esophagus after just one or two treatment sessions. The ability to eliminate more severe stages of Barrett's esophagus, specifically low-grade dysplasia and high-grade dysplasia, is very promising. Most importantly, these studies report a high degree of patient tolerability and safety. These results suggest great news for the large number of patients currently under surveillance for Barrett's esophagus who live with the fear of developing esophageal cancer."

Approximately one to two million adults in the United States are under regular surveillance, endoscopy with biopsy, for Barrett's esophagus. Caused by chronic GERD (gastroesophageal reflux disease), Barrett's esophagus is a precancerous condition affecting the lining of the esophagus, the muscular tube that carries food, liquids and saliva from the mouth to the stomach. Barrett's esophagus can lead to a dangerous type of cancer called esophageal adenocarcinoma, which is currently the most rapidly rising cancer in the U.S. With the Halo³⁶⁰ System, the thin layer of the diseased esophageal lining is completely removed.

About the Halo³⁶⁰ System

The BÂRRX Medical Halo³⁶⁰ System provides uniform and controlled ablative therapy at a consistent depth to remove the layer of the diseased esophageal tissue allowing replacement by normal cells. The procedure, which in clinical studies had a median procedure time of 26 minutes, is performed without incisions using conscious sedation in an out-patient setting. First, a physician uses a Halo³⁶⁰ sizing balloon catheter to dilate the esophagus and determine its inner diameter. A correctly sized ablation catheter is then inflated within the diseased area of the esophagus. The Halo³⁶⁰ energy generator is activated to deliver a rapid (less than one second) burst of ablative energy, which removes a very thin (less than one millimeter) layer of the diseased esophagus. Controlled delivery of energy avoids injury to normal, healthy underlying tissues. New healthy tissue replaces the ablated Barrett's tissue in three to four weeks for most patients, according to trial results. Minor discomfort, which may be experienced by some patients, has been managed in the trials with medication. Following ablation therapy, patients resume acid suppression therapy.

The device used in the clinical trials, presented at DDW, was cleared by the U.S. Food and Drug Administration in 2001 and became commercially available in January 2005.

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), the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW takes place May 14-19, 2005 in Chicago. The meeting showcases approximately 5,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology.

About BÂRRX Medical, Inc.

BÂRRX Medical, Inc. develops treatment solutions for Barrett's esophagus, a precancerous condition of the lining of the esophagus (swallowing tube) caused by gastroesophageal reflux disease, or GERD. Its flagship product, the Halo³⁶⁰ System, provides uniform and controlled therapy at a consistent depth, which can remove Barrett's esophagus and allow the regrowth of normal cells. In clinical studies, 75 percent of participants were Barrett's-free after one to two treatment sessions (at six-seven month follow up). The system used in the clinical trials was cleared by the U.S. Food and Drug Administration in 2001 and has been commercially available since January 2005. Based in Sunnyvale, Calif., BÂRRX Medical was founded in 2000 and is privately-held. Additional information about BÂRRX Medical and the Halo³⁶⁰ System is available at www.barrx.com.

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