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Data Evaluating Safety and Efficacy of the HALO³⁶⁰ System in Treating Barrett's Esophagus Presented at the American College of Gastroenterology Annual Meeting

Studies Show 100% Clearance Rates for Barrett's Esophagus with Low Grade Dysplasia

HONOLULU, HAWAII—Booth #1515—ACG—October 31, 2005—BÂRRX Medical, Inc. today announced the results of a study presented by Virender K. Sharma, M.D. of the Mayo Clinic in Arizona, evaluating the safety, tolerability and effectiveness of the HALO³⁶⁰ System in the treatment of Barrett's esophagus with low grade dysplasia (LGD). The study results, presented at the American College of Gastroenterology Annual Meeting, October 28 thru November 2, 2005, demonstrate that all patients enrolled and treated have achieved complete resolution of LGD, a precancerous condition affecting the lining of the esophagus.

Nine male patients and one female patient with a mean age of 56 years and up to 6 cm of biopsy-proven Barrett's esophagus with LGD were enrolled in this study. After one or two treatments, histology from biopsies showed that all patients (100%) were completely free of LGD. The authors conclude that the HALO³⁶⁰ system allows for the complete and circumferential ablation of Barrett's esophagus with LGD without significant complications. As part of his presentation at the ACG, Dr. Sharma will also share data from a second study evaluating the use of the HALO³⁶⁰ system in patients with high grade dysplasia (HGD), an even more advanced disease state with a poor prognosis and limited treatment options. This data also shows encouraging results associated with HGD.

“As recently discussed in the *Wall Street Journal*, Barrett's esophagus is a serious health condition and a known precursor to esophageal adenocarcinoma, a dangerous form of cancer with a rapidly rising incidence in the United States,” said David S. Utley, M.D., Chief Medical Officer, BÂRRX Medical, Inc. “Dr. Sharma's findings are an important addition to the rapidly accumulating set of data supporting the safety and efficacy of the HALO³⁶⁰ system in treating dysplastic and non-dysplastic Barrett's esophagus.”

“Patients who are diagnosed with Barrett's esophagus and either LGD or HGD are particularly at risk for cancer development,” states Dr. Sharma. “Once dysplasia occurs, we must remain particularly vigilant for cancer for the lifetime of the patient. As with the

precancerous colon polyp, it makes logical sense that if we can eliminate the Barrett's dysplasia completely and safely, we should do so in order to reduce the risk for developing cancer.”

Approximately 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. The HALO³⁶⁰ system, a second-generation ablation device, removes the thin layer of diseased esophageal tissue allowing the regrowth of normal cells.

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.

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, the majority of participants were Barrett's-free after one to two treatment sessions. 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, Inc. was founded in 2000 and is privately-held. Additional information about BÂRRX Medical, Inc. and the HALO³⁶⁰ system is available at www.barrx.com.

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