

## For Immediate Release

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## **Definitive outcomes of radiofrequency ablation for Barrett's esophagus using the HALO ablation system reported at the Digestive Disease Week meeting for gastroenterologists and esophageal surgeons**

*Radiofrequency ablation is durable after 2 years, compares favorably with endoscopic resection for advanced disease, and reduces the risk for cancer progression*

**Sunnyvale, CA, Wednesday June 3, 2009, 1 pm EDT:** Results from a number of clinical trials were presented during the Digestive Disease Week (DDW) in Chicago this week, revealing new outcomes data related to endoscopic radiofrequency ablation using the HALO ablation system for eradicating a pre-cancerous esophageal condition known as Barrett's esophagus. Among them, reports included durability outcomes from a randomized sham-controlled trial, safety and efficacy outcomes from a large U.S. registry of 429 patients, a randomized trial comparing ablation to endoscopic resection, and the largest European series to date in patients with high-grade dysplasia and early cancer.

As the DDW meeting commenced, the *New England Journal of Medicine* published a landmark paper entitled, "**Radiofrequency Ablation for Barrett's Esophagus Containing Dysplasia.**" This is a U.S. randomized sham-controlled trial demonstrating high rates of complete eradication of Barrett's and dysplasia in the ablation group as compared to control, as well as a significant reduction in cancer progression. At DDW, researchers presented new data from this now published trial, showing that the ablation effect achieved at 1 year follow-up was highly durable at the 2-year follow-up.

In the largest patient series to date, "**Radiofrequency Ablation of Barrett's Esophagus: Outcomes of 429 Patients from a Multi-center Community Practice Registry,**" U.S. investigators reported a low stricture risk (about 1%) and no serious adverse events. After an average of 2 ablation procedures using the HALO ablation system and 20-month follow-up, 77% of patients were cured of their Barrett's disease. For those patients that had baseline evidence of dysplasia, 100% had complete eradication of all signs of dysplasia. These data comport with published data from predominantly tertiary referral centers.

A European multi-center randomized trial included 47 patients with Barrett's containing dysplasia and early cancer that were randomized to receive either endoscopic resection or radiofrequency ablation with the HALO ablation system. While both interventions had very high complete eradication rates (95-100%), endoscopic resection was associated with a significantly higher risk of complications. Based on these results, investigators concluded that the optimal approach is to focally resect visible lesions followed by radiofrequency ablation for complete eradication of the remaining Barrett's tissue.

In the largest European series reported to date, "**Radiofrequency Ablation for Eradication of Barrett's Esophagus Containing High-Grade Dysplasia or Early Cancer: A Prospective Series of 73 Patients,**" researchers combined a baseline focal

endoscopic resection for disease staging, and then applied serial RFA with the HALO ablation system. A complete response was achieved in 95% of patients without occurrence of serious adverse events.

“Barrett’s esophagus places a patient at a significantly higher risk for developing esophageal adenocarcinoma,” commented David S. Utley, M.D., chief medical officer for BARRX Medical. “Researchers at this national meeting are reporting the results of a number of well-designed clinical trials using endoscopic radiofrequency ablation to completely eradicate the Barrett’s tissue. Each unique study design offers new data that continues to establish an evidence-based role for radiofrequency ablation in managing this disease state.”

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### **About BARRX Medical, Inc.**

BARRX 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 main product, the HALO<sup>360</sup> System, provides a uniform and controlled ablation effect, which removes the diseased tissue and allows regrowth of normal cells. The HALO<sup>90</sup> System is the company’s second ablation product, which is mounted on the end of an endoscope and used to treat smaller, non-circumferential areas of disease.

A multi-center randomized, sham-controlled study, published in the *New England Journal of Medicine*, studied radiofrequency ablation applied in the highest risk Barrett’s population (those having dysplasia). The ablation group had a high rate of complete eradication of dysplasia and intestinal metaplasia and a significantly decreased rate of disease progression and cancer development, as compared to the control group. In another study (AIM-II) published in *Gastrointestinal Endoscopy*, 98.4% of patients were Barrett’s-free after two and a half years of follow-up.

Both HALO systems are cleared by the FDA for use in the U.S. and both have CE Mark for use in Europe. More than 30,000 procedures have been performed in over 280 hospitals around the world. Based in Sunnyvale, Calif., BARRX Medical, Inc. was founded in 2000 and is privately-held. Additional information is available at [www.barrx.com](http://www.barrx.com).

### **About Digestive Disease Week**

Digestive Disease Week (DDW) is the largest international gathering of physicians, researchers, and academicians 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 30 – June 4, 2009 in Chicago, IL. The meeting presents approximately 5,000 abstracts and hundreds of lectures on the latest advances in GI research and technology.

A list of all scientific presentations related to radiofrequency ablation for Barrett’s esophagus can be found at [www.barrx.com](http://www.barrx.com)