

For Immediate Release

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Study in the *New England Journal of Medicine* shows non-surgical treatment for pre-cancerous condition of esophagus is effective and reduces risk for cancer development

Data show superiority of endoscopic ablation therapy using the HALO System for eradicating Barrett's esophagus in randomized, multicenter, sham controlled trial

Sunnyvale, CA, May 27, 2009, 5 pm EDT: Results from a clinical study published today in the *New England Journal of Medicine* reveal that ablative therapy using the HALO system (BÂRRX Medical, Inc.) is highly effective for complete eradication of a pre-cancerous condition of the esophagus called Barrett's esophagus afflicting more than 3.3 million Americans. Additionally, ablative therapy using the HALO system reduced the risk of progression to cancer in the highest risk cohort studied (compared to control) from 19.0% to 2.4%.

The study entitled "**Radiofrequency Ablation in Barrett's Esophagus with Dysplasia**" is authored by lead investigator Nicholas J. Shaheen, M.D., Associate Professor of Medicine and Epidemiology, The University of North Carolina in Chapel Hill.

"This is a well-designed trial conducted in a rigorous manner at 19 expert U.S. centers, each having experience in the management of Barrett's esophagus, dysplasia, and cancer," said Dr. Shaheen. "Our results reported in the *Journal* are very promising, demonstrating superiority of ablation therapy for eliminating Barrett's and dysplasia, as well as reducing the rate of disease progression to more severe forms of dysplasia and esophageal cancer. This and data from other recent trials may ultimately change the paradigm for how gastroenterologists manage their patients with this disease."

As a result of chronic injury from gastroesophageal reflux disease (GERD), the normal esophageal lining is replaced with abnormal cells (Barrett's tissue), predisposing the patient to a higher risk for developing cancer of the esophagus. Patients with Barrett's who develop cancer, typically do so through a series of steps, starting with early Barrett's, then low-grade dysplasia or high-grade dysplasia, and then finally cancer. The present study included patients with the later stages of low- and high-grade dysplasia.

Beginning in 2006, the AIM Dysplasia Trial enrolled 127 patients having a diagnosis of Barrett's esophagus with dysplasia, the most advanced stage of this condition. Patients were randomly assigned to receive either endoscopic ablation with the HALO system or a sham intervention (control, no treatment). Tissue samples (biopsies) were obtained from the esophagus at regular intervals for one year after enrollment to assess for the presence of early Barrett's, dysplasia, and esophageal cancer. Comparison of the biopsy results at one year served as the primary outcome for the trial. The study endpoints were the eradication of all early Barrett's and, separately, all dysplasia in each group, as well as occurrence of new esophageal cancers.

At one-year follow-up, patients treated with ablation had a significantly higher complete eradication rate for both early Barrett's and dysplasia as compared to the control group. More than three quarters of treated patients had no detectable Barrett's at the end of the treatment period, compared to sham patients where 98% had persistent disease. The overall rate of disease progression to more severe forms of dysplasia and cancer was significantly lower in the ablation treatment group (3.6%) as compared to the control group (16.3%). In the highest risk cohort (high-grade dysplasia), ablative therapy significantly reduced the risk of progression to cancer by nearly 90% compared to control (2.4% in treated patients versus 19.0% in untreated controls).

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 HALO³⁶⁰ System, provides a uniform and controlled ablation effect, which removes the diseased tissue and allows regrowth of normal cells. In the largest clinical trial conducted and published to date (the AIM-II Trial), 98.4 percent of patients were Barrett's-free after two and a half years of follow-up. The HALO⁹⁰ 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.

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.

About the *New England Journal of Medicine*

The *New England Journal of Medicine* (N Engl J Med or NEJM) is an English-language peer-reviewed medical journal published by the Massachusetts Medical Society. It is one of the most popular and widely read peer-reviewed general medical journals in the world. It is also the oldest continuously published medical journal in the world. The journal usually has the highest impact factor of all journals of clinical medicine; in 2006, the impact factor was 51, according to *Journal Citation Reports*, the first research journal to break 50.