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Presentation of Landmark Clinical Trial Evaluating Endoscopic Treatment for Pre-cancerous Condition of Esophagus

Superiority of Ablation Therapy Using HALO System Demonstrated for Eradicating Barrett's Esophagus and Reducing Risk for Disease Progression

San Diego, CA—Booth #2349—Digestive Disease Week—May 19, 2008—BARRX Medical, Inc., a technology leader in the design and manufacture of medical devices for digestive diseases, today announced the presentation of a landmark study entitled, **“A Randomized, Multicenter, Sham-Controlled Trial of Radiofrequency Ablation (RFA) for Subjects with Barrett's Esophagus (BE) Containing Dysplasia: Interim Results of the AIM Dysplasia Trial.”** The study was presented by Nicholas J. Shaheen, M.D., Associate Professor of Medicine and Epidemiology, The University of North Carolina, during the clinical plenary session of the American Gastroenterological Association at the Digestive Disease Week meeting in San Diego, California.

“This is a very well-designed trial conducted in a rigorous manner at 19 expert U.S. centers, each having experience in the management of Barrett's esophagus and dysplasia,” said Dr. Shaheen. “Our interim results are highly promising, demonstrating superiority for ablation therapy for eliminating Barrett's and dysplasia, as well as reducing the risk for disease progression. Although we continue to complete the trial, these results may ultimately change the paradigm for how gastroenterologists manage their patients with Barrett's esophagus.”

Beginning in 2006, the AIM Dysplasia Trial enrolled 127 patients with a diagnosis of dysplastic Barrett's esophagus, the most advanced stage of this precancerous condition. As a result of injury from gastroesophageal reflux disease or 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 Barrett's, then Barrett's with low-grade dysplasia (minor pre-cancerous changes) or high-grade dysplasia (severe pre-cancerous changes), and then finally cancer. The present study included patients with Barrett's containing low- or high-grade dysplasia.

Patients in the study were randomly assigned to receive either endoscopic ablation therapy using the HALO ablation system (BARRX Medical, Inc.), or, a sham (placebo) intervention. Tissue samples, or biopsies, were subsequently taken at regular intervals over the next year to assess for Barrett's, dysplasia, and / or cancer. Comparative pathology results at one year served as the primary outcome for the trial. The study endpoints were the disappearance of dysplasia, as well as the more rigorous endpoint of complete eradication of all Barrett's tissue. In the latter case, the esophageal lining is deemed normal, with no sign of residual abnormal cells.

At one year follow-up, the treatment group had a much higher complete eradication rate for both dysplasia and Barrett's cells as compared to the untreated sham group, with statistical significance. In fact, more than three quarters of the treated patients had no detectable Barrett's at the end of the treatment period, compared to sham patients (all of whom still had Barrett's.) Further, the progression rate to higher grades of dysplasia and esophageal cancer was significantly lower in the treatment group as compared to the sham group.

About BARRX Medical and the HALO Ablation Technology

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 flagship product, the HALO³⁶⁰ System, provides uniform and controlled therapy at a consistent depth, which can remove Barrett's esophagus and allow the re-growth of normal cells. In the largest clinical trial conducted and published to date (the AIM Trial), 98.4 percent of patients were Barrett's-free after two and a half years. 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. The HALO⁹⁰ System 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, was introduced in 2007. More than 14,000 procedures have been performed in over 200 hospitals around the world. Based in Sunnyvale, Calif., BARRX Medical, Inc. was founded in 2000 and is privately-held. Additional information about BARRX Medical, Inc. and the HALO ablation system of products is available at 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 17-22, 2008 in San Diego, CA. The meeting showcases approximately 5,000 abstracts and hundreds of lectures on the latest advances in GI research and technology.