HIGHLIGHTS FROM DIGESTIVE DISEASE WEEK, SAN DIEGO, 2008

Demonstrate Clinical Utility of Cellvizio® GI in Diagnosing Colorectal Cancer and Barrett's Esophagus

Cellvizio GI Enables Immediate Diagnosis of Colorectal Lesions with Malignant Potential and Distinguishes Them from Nonneoplastic Polyps with High Accuracy Level

International gastroenterologists presented data from four clinical studies on Cellvizio® GI at the Digestive Disease Week® (DDW) 2008 conference in San Diego. The reported data demonstrate Cellvizio GI's value in diagnosing colorectal cancer as well as other gastrointestinal diseases. A fundamentally new endoscopic imaging approach, Cellvizio could improve patient care by eliminating unnecessary biopsies and could further improve diagnostic rates across a broad range of diseases.

"This new evidence should lead to broader use of Cellvizio GI in the clinic as an essential tool for improving the diagnosis of a broad range of gastrointestinal diseases," said Sacha Loiseau, Ph.D., president and CEO of Mauna Kea Technologies. "The studies also highlight the technology's compatibility with other gastrointestinal diagnostic tools and its potential for improving the detection rate of gastrointestinal cancers."

In an oral presentation, Anna Buchner, M.D., Mayo Clinic, Jacksonville, Fl., U.S.A., discussed the results of a 26-patient study assessing Cellvizio GI's applicability for diagnosing benign and malignant lesions in colorectal polyps during colonoscopy screening. The trial found that the technology predicted the presence of premalignant, advanced colorectal lesions and malignant lesions with a high accuracy of 86.5% (CI 75.5%–97.5%), sensitivity of 82.6% (CI 68.9%–86.7%), and specificity of 92.9% (CI 70.3%–99.6%).

A poster presentation (S1169) on an ongoing study of ulcerative colitis patients by Pr. Frank J van den Broek, Academic Medical Center; Amsterdam, Netherlands, concluded that Cellvizio makes it feasible to recognize histological features *in vivo* and may eliminate the need for random biopsies and unnecessary biopsies from lesions without tumors. Nine patients and a total of 57 colonic areas have so far been examined. After inspection with the Cellvizio GI, normal colonic tissue was found in 33 specimens; inflammation in 11 specimens; hyperplasia changes in 9; and intraepithelial tumors in 4.

A poster presentation (S1392) on a study by Heiko Pohl, M.D., VA Medical Center, White River Junction, VT, concluded that Cellvizio GI is highly effective at identifying which Barrett's esophagus patients do not have advanced growth of precancerous cells in their esophagus. The 38-patient study compared Cellvizio GI's ability to accurately diagnose the degree of precancerous tissue in patients with Barrett's esophagus compared to histology results of biopsies taken from the same areas. Cellvizio evaluation by two independent examiners to detect advanced neoplasia was accurate in 88% to 93%, and showed a sensitivity and specificity between 75% and 80%, and 89% and 94%, respectively, translating at best into a low positive predictive value of 44.4% and a high negative predictive value of 98.8%.

A poster presentation (M1316) by Rami J. Badreddine, Mayo Clinic, U.S.A., described the results of a study of 62 patients with a history of Barrett's esophagus with high-grade dysplasia or early adenocarcinoma. Results showed that in patients with flat normal appearing mucosa, Cellvizio GI guided EMR detected high-grade in a significantly higher number of patients compared to just surveillance biopsies (55% vs. 23%, $p<0.03$). The detection rate of high-grade dysplasia or cancer Cellvizio GI targeted EMR in flat normal appearing mucosa was similar to that found in nodular mucosa (55% vs. 61%, $p<0.75$).

Cellvizio is compatible with most endoscopes and allows physicians to view live tissue inside the body at the cellular level in dynamic, real-time images at 12 frames per second. Over 1,000 Cellvizio procedures have been completed to date. It has 510(k) clearance from the Food & Drug Administration and the European CE-Mark for use in the gastrointestinal and pulmonary tracts.

TAP Pharmaceutical Products Inc. Announces Phase 3 TAK-390MR Data Demonstrating Higher Overall Healing Versus Lansoprazole in Patients with Erosive Esophagitis

Additional Data Demonstrated Higher Overall Maintenance of Healed Erosive Esophagitis and Symptom Relief versus Placebo

TAP Pharmaceutical Products Inc. reported results from three pivotal Phase 3 studies evaluating investigational new drug TAK-390MR, a proton pump inhibitor (PPI) with an innovative dual delayed release technology, in healing patients with erosive esophagitis (EE) and in maintenance of healed EE.

"The innovative dual delayed release technology delivers TAK-390MR in two separate releases, which is a first in the PPI class and makes TAK-390MR a very interesting potential future treatment option," said Dr. David Peura, professor of medicine, University of Virginia Health System, past president of the American Gastroenterological Association.

Data from the two separate EE healing studies demonstrated that patients treated with TAK-390MR 60 mg and 90 mg experienced higher overall healing after eight weeks, versus patients taking lansoprazole 30 mg. In addition, data from a six-month maintenance of healed EE study demonstrated that patients treated with TAK-390MR 30 mg and 60 mg experienced statistically significant overall maintenance and symptom relief over placebo.

Pivotal Study Shows Physician/Nurse Teams Using Sedasys™ System Reduced Risk of Over Sedation with Propofol

Ethicon Endo-Surgery announced that the results from its pivotal trial demonstrated physician/nurse teams using the SEDASYS System reduced the risk of over sedation with propofol in patients undergoing screening and diagnostic procedures for colorectal cancer (colonoscopy), and disorders of the upper gastrointestinal tract (EGD). The study—presented at Digestive Disease Week—included 1,000 subjects who underwent sedation for colonoscopy and EGD at eight sites and compared the SEDASYS System to the current standard of care for sedation (midazolam plus fentanyl or meperidine). Results were included in Ethicon Endo-Surgery's PreMarket Application (PMA) for approval of the SEDASYS System, which is currently in review with the U.S. Food and Drug Administration.

"During the trial, the system made it possible for gastroenterologists to maintain minimal to moderate sedation with propofol, and helped prevent patients from entering deep sedation, which is traditionally associated with propofol," said Daniel Pambianco, MD, F.A.C.G., medical director of Charlottesville (Va.) Medical Research and trial investigator. "The system offers a way to personalize the level of sedation appropriate for each patient because it combines propofol delivery with sophisticated monitoring to help us better control and predict the patient's sedation level."

Patients who received sedation with the SEDASYS System experienced fewer and less significant oxygen desaturation events, a clinical sign of over sedation, than patients sedated with current standard of care. The trial demonstrated this by achieving its primary endpoint of Area Under the Curve (AUC) of oxygen desaturation (SpO2 < 90%). AUC is an objective measure of a patient's respiratory status that incorporates incidence, duration and depth of oxygen desaturation. Patients in the SEDASYS System group had an average AUC value of one-third less than the current standard of care patients. No device-related adverse events occurred in patients sedated with the SEDASYS System.

Colonoscopy is considered the gold standard for detecting colorectal cancer, the second-leading cause of cancer-related deaths in the United States. The American Cancer Society is calling for increased colorectal cancer screening and recommends that people aged 50 and older receive regular screenings.

"Patients understand that recovery from sedation takes time after a colonoscopy, but with propofol, they recuperate quicker and are functional sooner," said Dr. Pambianco. "GIs have been performing procedures with current standard of care sedatives for years and maintaining a constant sedation level in patients can be daunting. The novelty of this system is that it has the potential to accurately tune into my patient's sedation needs by following their vital signs and delivering propofol in a precise manner."

The SEDASYS System is the first computer-assisted personalized sedation (CAPS) system

designed for physician/nurse teams to provide minimal to moderate sedation levels with propofol. By integrating drug delivery and patient monitoring, the SEDASYS™ System enables physician/nurse teams to deliver personalized sedation. The device continuously monitors and records six patient parameters including oxygen saturation, respiratory rate, heart rate, blood pressure, end-tidal carbon dioxide and patient responsiveness. It automatically detects and responds to signs of over sedation (oxygen desaturation and low respiratory rate/apnea) by stopping or reducing delivery of propofol, increasing oxygen delivery and automatically instructing patients to take a deep breath. The device is currently an investigational device limited by U.S. law to investigational use only.

Analysis of Ulcerative Colitis (UC) Time to Symptom Resolution Data from Pivotal Study of Lialda™ (Mesalamine) Presented at DDW

A post hoc analysis showing time to symptom resolution data from a study (study 302) of Shire plc's ulcerative colitis (UC) drug, Lialda™, was presented at Digestive Disease Week (DDW). Study 302 (further referred to as "Kamm study," led by Dr Michael A. Kamm, from St Mark's Hospital in London, UK), demonstrated Lialda™ was effective in inducing remission in patients with active, mild to moderate ulcerative colitis compared to placebo and these study results were published in the January 2007 issue of *Gastroenterology*.

"The time between initiation of therapy and initial symptom resolution is an important endpoint in the treatment of UC for both patients and physicians," said Gary Lichtenstein, director of the Inflammatory Bowel Disease Program at the University of Pennsylvania, investigator on this post hoc analysis. "This analysis was important as it showed Lialda™ benefits patients by significantly lowering the time it takes patients to experience relief from their UC symptoms as compared to placebo."

Study Presented at DDW 2008 Confirms that New Device Significantly Improves Detection of Polyps in the Colon

A study presented by Jerome D. Waye, MD, from the Mount Sinai Hospital in New York and principal investigator of the study, showed that the Third Eye Retroscope™, developed by Avantis Medical Systems, Inc. of Sunnyvale, CA, when used in combination with a standard colonoscope, detects a significantly higher number of adenomas and other polyps than the colonoscope alone. The Third Eye Retroscope has been cleared for use in the U.S. by the Food and Drug Administration (FDA).

The multi-center study evaluated 214 patients at eight sites across the United States. Used during colonoscopy, the Third Eye Retroscope is an auxiliary imaging device that provides retrograde illumination and visualization of the colon for diagnostic purposes. The device is passed through the instrument channel of a standard colonoscope until it extends beyond the tip of the colonoscope. As it emerges, the device turns around 180 degrees to provide a continuous retrograde view while the colonoscope is being withdrawn.

The study (which is ongoing) has found that, in combination with a standard colonoscope, the Third Eye Retroscope detected 13.3 percent additional polyps, and 12.4 percent additional adenomas, compared with the colonoscope alone. Polyps detected with the Third Eye were comparable in size with those seen with the endoscope.

"Our investigators are finding that the Third Eye Retroscope is a promising new technology for improving visualization during colonoscopy," said Dr. Waye, "During the Study, the Third Eye revealed areas that are often hidden from the forward-viewing colonoscope and it allowed a significant increase in detection of adenomas and other polyps." ■

Conservative Treatment of Infant GERD

Gastroesophageal reflux disease (GERD) is a relatively common problem in infants. Limited drug trials have been performed in this age group, and there is evidence to suggest that conservative management for infant GERD may be very efficacious for disease management. Infants were recruited from five outpatient clinics in Pittsburgh, Pennsylvania over a two-month period and were evaluated prior to entering a prospective, placebo-controlled, double-blinded study of a H_2 receptor agonist. A total of 40 infants met inclusion criteria and were scored using the Infant Gastroesophageal Reflux Questionnaire Revised scale (I-GERQ-R). Conservative therapy, including formula change (elemental feeds for formula-fed infants and avoidance of cow's milk and soy milk by mothers of infants that were breast fed), judicious use of rice cereal as a thickening agent, avoidance of seated or supine positioning unless in a car seat or sleeping, and avoidance of tobacco exposure were instituted at baseline and followed up after two weeks of therapy.

Thirty-seven infants returned for the two-week visit, and these infants had a median age of 13 weeks with a range of four to 43 weeks. The study group had 59% male infants of which the ethnic demographics included 68% white, 16% African-American, and 16% Hispanic infants. At this follow-up visit, 78% of infants had an improvement in their I-GERQ-R, and 59% of study subjects had a score change of at least five points which was associated with an improved clinical change, including a decrease in vomiting, crying, and back arching. This change was not dependent on study subject age, suggesting that infant physiologic maturation was not a cause of the improved scoring. This study elegantly emphasizes the importance of lifestyle change in the treatment of infant GERD and emphasizes the need for placebo-controlled trials using conservative managment for GERD in this age group. (Orenstein SR, McGowan JD. "Efficacy of conservative therapy as taught in the primary care setting for symptoms suggesting infant gastroesophageal reflux." *J Pediatircs*, 2008;Vol.152: 310-314).

Biliary Atresia: Is Mom to Blame?

Biliary atresia (BA) is the most common cause of liver transplant in infants, and its cause is essentially unknown although there appears to be an immunologic basis of the disease which may be autoimmune or infectious. In Japan, eight male infants with BA had their liver tissue compared to six male infants with liver disease from other causes, including hereditary tyrosinemia, choledochal cyst, congenital absence of the portal vein, hepatic hemangioendothelioma, and Crigler-Najjar syndrome. All liver tissue specimens underwent *in situ* hybridization for determination of XX chromosome-containing cells as well as immunohistochemistry staining for CD8, CD4, CD45, CD79a, and cytokeratin to look for a maternal immune response.

In patients with BA, portal tissue and bile duct epithelium had increased numbers of CD8 and CD79a lymphocytes. Lymphocytes containing XX chromosomes were significantly higher in number in patients with BA compared to those patients with other liver diseases. Interestingly, although the proportion of CD8, XX-containing lymphocytes was ten times higher in BA patients compared to the control group, the total number of CD8 cells was lower in BA patient samples compared to the control group. These data point strongly to an immune response from chimeric maternal cells which may cause BA. The authors point out that the pathogenesis of BA may be better defined as a "maternofetal immune disease." (Muraji T, Hosaka N, Irie N, Yoshida M, Imai Y, Tanaka K, Takada Y, Sakamoto S, Haga H, Ikehara S. "Maternal microchimerism in underlying pathogenesis of biliary atresia: quantification and phenotypes of maternal cells in the liver." *Pediatrics*, 2008; Vol. 121: 517-521).

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PRACTICAL GASTROENTEROLOGY

New Data Show High Frequency of Medical Claims for Gastrointestinal Events by Patients on Antiplatelet Therapy

Review of Insurance Claims Tracked Ulcers and Bleeding Among 368,000 Patients Prescribed Clopidogrel

A review of medical claims from more than 70 managed care plans showed that 6.2% of patients prescribed the antiplatelet medicine clopidogrel submitted at least one insurance claim for ulcer or gastrointestinal bleeding, according to data released by Cogentus Pharmaceuticals, Inc. at the annual meeting of the International Society for Pharmacoeconomics and Outcomes Research.

Clopidogrel, marketed as Plavix®, is among the world's largest-selling prescription medicines and is prescribed to prevent heart attacks and strokes. The retrospective study reported today tracked insurance claims for gastrointestinal adverse events among more than 368,000 patients in the 12 months following their first prescription for clopidogrel.

"This study provides important new information about the frequency of medical attention for gastrointestinal events required by an insured population on antiplatelet therapy," said lead author Dr. Pablo Lapuerta, Chief Medical Officer and Senior Vice President for Clinical Strategy at Cogentus.

"Inhibition of normal platelet function by clopidogrel likely contributed to gastrointestinal complications, particularly in such a real-world setting in which patients often have multiple risk factors," he said. "While it is important for patients to stay on clopidogrel to prevent the progression of coronary heart disease, ulcers and bleeding can result in patients not taking their heart disease medicine."

Experts believe that multiple factors contribute to ulcer disease and its complications. Studies have shown an increased risk of gastrointestinal bleeding among patients using antiplatelet medicines such as clopidogrel or aspirin, and an even higher risk for patients taking clopidogrel in combination with aspirin or other non-steroidal anti-inflammatory drugs (NSAIDS). One study showed that treatment with clopidogrel augmented bleeding caused by NSAIDS, an effect attributed to the inhibition of platelets by clopidogrel.

Increasing age is a recognized risk factor for ulcer disease, and clopidogrel is commonly prescribed for elderly patients with atherosclerosis. In the insurance claim review, 72% of patients were over 60 years of age. Information about concurrent aspirin use, which is common among patients with cardiovascular disease and particularly among clopidogrel users, was not available. A higher incidence of bleeding side effects was seen in women (7.2%) filed medical claims for an ulcer or gastrointestinal bleeding while 5.4% of men filed claims.

"The surprisingly high frequency of these claims raises a significant public health concern," said Dr. Byron Cryer, the John C. Vanatta III Professor of Medicine and Associate Dean for Minority Affairs at Southwestern Medical School in Dallas. "Until recently, gastrointestinal side effects in patients taking antiplatelet therapy have been largely underappreciated by physicians, who are appropriately focused on preventing future heart attacks. We need to address this problem to help keep patients on their medical treatment regimens."

Dr. Cryer is a member of the Scientific Steering Committee overseeing COGENT, the global Phase 3 clinical trial program sponsored by Cogentus. The COGENT program will evaluate the efficacy and safety of Cogentus's lead product, CGT-2168, which combines clopidogrel and the gastroprotectant omeprazole. CGT-2168 is designed to maintain the cardiovascular benefits of antiplatelet therapy while reducing its potentially serious gastrointestinal side effects.

Patients at Long-term Care Facilities Could Benefit from Yeast-based Probiotic

Clinical Evidence Shows that Use of Florastor® Can Reduce C. diff*-Associated Disease Recurrence by Half; Manufacturer Introduces 200-Count Pack for Institutional Settings*

Clostridium difficile-associated disease (CDAD), which ranges from mild diarrhea to severe colitis and death, is brought on by the *Clostridium difficile* (*C. diff*) pathogen, and has been the subject of new heightened concern in the medical community. A new report released this month by the Federal Agency for Healthcare Research and Quality (AHRQ) reveals a 200% increase in potentially fatal diarrheal infections in U.S. hospitals between 2000 and 2005. Furthermore, other

research has shown that that approximately one in four CDAD patients will experience a recurrence of symptoms even after one round of potent antibiotic therapy.

On average, patients with CDAD were hospitalized almost three times longer than uninfected patients, and two out of the three infected hospital patients in 2005 were elderly, according to the AHRQ report. Hospitals and long-term care facilities appear to be the major reservoirs for *C. diff*. The organism can be cultured from residents with and without diarrhea, from the environment of infected residents, to include bedpans, bedrails, bedside commodes, wheelchairs, etc., and from the hands of health care workers caring for these residents. The heat-resistant spores can survive for weeks and months in the environment.

CDAD is treatable with powerful antibiotics, such as metronidazole or vancomycin, but because *C. diff* is a spore-producing pathogen, patients often suffer from relapse when the spores "hatch" weeks or even months later.

However, relief from recurrence can be found for many—approximately half—with the help of a particular probiotic. *Saccharomyces boulardii* (*S. boulardii*) is the only yeast-based probiotic clinically shown to be effective against a recurrence when used in conjunction with the second round of antibiotic therapy. Because of this compelling data, Biocodex Inc., maker of Florastor®, has introduced a new institution-size box of easy-to-administer, individual powder packets (200 count) for use in hospitals and long-term care facilities, where the threat of CDAD is highest based on population demographics and environment.

"When a relapse occurs, use of Florastor during the second antibiotic course can help protect against future relapses because it colonizes the gut with *S. boulardii*, which can help fight recurrent *C. diff*," says Patricia Raymond, MD, FACP, FACG, a Chesapeake, Virginia-based gastroenterologist, associate professor of clinical medicine at Eastern Virginia Medical School and host of the National Public Radio program, HouseCalls. "Better yet, because *S. boulardii* is a yeast and not a bacterial-based probiotic, it is not killed by the strong antibiotics that are being taken to eradicate the *C. diff* bacteria, so it survives in the digestive tract effectively."

A recent meta-data analysis of 31 studies compiled and published in the *American Journal of Gastroenterology* concluded that *S. boulardii* is the only probiotic that is effective in fighting recurrent *C. diff*-associated disease (CDAD) (1). Additionally, an article in the March 2006 issue of *Gastroenterology and Hepatology* showed that use of *S. boulardii* provided an almost 50% decrease in subsequent recurrence among patients who suffered recurrent CDAD symptoms (2). *S. boulardii* is also mentioned by the World Health Organization for use in the management of *C. diff*-associated disease (3).

One key population that can benefit from taking Florastor is patients with enteral feeding, many of whom develop diarrhea. A study published in a 1997 issue of *Intensive Care Medicine* concludes that *S. boulardii* can prevent diarrhea in critically ill tube-fed patients, especially those with risk factors for diarrhea (4).

Sources

1. McFarland, L.V. (2006). Meta-analysis of probiotics for the prevention of antibiotic- associated diarrhea and the treatment of Clostridium difficile disease. *American Journal of Gastroenterology.* 101, 812-822.
2. Huebner, E.S., & Surawicz, C.M. (2006). Treatment of recurrent Clostridium difficile diarrhea. *Gastroenterology and Hepatology.* 2, 203-208.
3. Saccharomyces boulardii: a valuable adjunct in recurrent Clostridium difficile disease? (1995) *WHO Drug Information;* 9;(1); 15-16.
4. Saccharomyces boulardii prevents diarrhea in critically ill tube-fed patients (1997) *Intensive Care Medicine,* 23: 517-523

Cimzia® Approved in the U.S. for the Treatment of Moderate to Severe Crohn's Disease

Administered Every Four Weeks, UCB's Pegylated Anti-TNFα Offers New Treatment Pption for Patients with Moderate to Severe Crohn's Disease; Cimzia® Will be Available in the U.S. Within the Next 48 Hours

The U.S. Food and Drug Administration (FDA) has approved Cimzia (certolizumab pegol), a PEGylated anti-TNFα (Tumor Necrosis Factor alpha) antibody indicated for reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderate to severe active disease who have an inadequate response to conventional therapy.

"Cimzia is a UCB biological innovation that will provide a monthly treatment option for patients suffering from Crohn's disease.

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The approval of Cimzia was based on safety and efficacy data from clinical trials in more than 1,500 patients with Crohn's disease. Each pivotal study demonstrated that a statistically significant greater proportion of moderate to severe Crohn's disease patients achieved and sustained clinical response with Cimzia for up to six months, compared to placebo. These data also showed that of the patients who were in remission after initial dosing, the majority maintained remission with no dose escalation.

Cimzia is the only PEGylated anti-TNFα. Cimzia is dosed subcutaneously every four weeks after initial dosing, making it a convenient option for people with moderate to severe Crohn's. Cimzia has demonstrated a low incidence of injection site reactions and injection site pain in clinical trials. The most common reported adverse events in the pivotal studies were upper respiratory tract infection (cold, flu), urinary tract infection (bladder infection) and joint pain. As seen with the use of the other anti-TNFα agents, serious, but infrequent infections and malignancies have been reported.

"The clinical trials program has shown Cimzia to be an effective subcutaneously-administered treatment, with a low rate of injection site reactions," said Stephen Hanauer, M.D., Professor of Medicine and Clinical Pharmacology at the University of Chicago. "The approval of Cimzia provides a new option for people with Crohn's disease to achieve relief from this debilitating condition with a convenient, stable administration once every four weeks."

Radiofrequency Ablation is Effective Treatment for Dysplasia in Barrett's Esophagus

Interim results from a nationwide clinical trial led by a University of North Carolina at Chapel Hill researcher suggest that radiofrequency ablation is an effective treatment for dysplasia in people with Barrett's esophagus, a condition that can lead to deadly gastrointestinal cancer.

"The interim results show there is a substantial difference between treatment with radiofrequency ablation and a placebo or 'sham' treatment," said Dr. Nicholas Shaheen, principal investigator of the study and director of UNC's Center for Esophageal Diseases and Swallowing. "It's a strongly positive finding." Shaheen is also an associate professor of medicine and epidemiology in UNC's Schools of Medicine and Public Health.

Barrett's esophagus is a condition in which repeated acid reflux causes the cells that normally line the esophagus to be replaced by a different type of cell, similar to those normally found in the intestines. This process is called intestinal metaplasia. By itself Barrett's is not a life-threatening problem, but a small percentage of people with Barrett's will develop esophageal adenocarcinoma, an especially deadly form of cancer.

Radiofrequency ablation, a non-invasive technique that uses thermal energy, or heat, to destroy cells, is very effective at destroying abnormal cells in the esophagus. The new UNC-led study is the first randomized trial to evaluate radiofrequency ablation for treating dysplasia, a more advanced stage of Barrett's esophagus in which the abnormal cells acquire precancerous traits.

The radiofrequency ablation system used in the study uses thermal energy provided by a set of electromagnetic coils on the surface of a balloon, Shaheen said. "The balloon is placed in the area of the esophagus where the offending cells are and the balloon is inflated. Energy is then passed through the electromagnetic coils and, because we know how far apart the coils are spaced and how much energy is being put through them, we get a very reliable depth of burn, such that you can kill the abnormal cells on the inner surface without damaging the whole organ."

In the study to date, 127 people were randomized to receive either radiofrequency ablation or a simulated, "sham" version of the procedure at one of 19 participating medical centers. Among those who received radiofrequency ablation, 85% were free of dysplasia 12 months after treatment. Seventy-four percent had no evidence of Barrett's at all in their biopsies. In comparison, none that received sham treatment were free of Barrett's.

The study will be completed in June 2008. It was funded by BARRX Medical Inc., which manufactures the HALO360 radiofrequency ablation system used in the study. ■