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Third Eye® Retroscope® Demonstrates Effectiveness for Detecting Polyps in the Right Colon

Data Presented at Digestive Disease Week 2009

SUNNYVALE, CA – Wednesday, June 3, 2009 – Avantis Medical Systems, Inc., a technology leader in developing novel chip-on-catheter digital imaging devices, today announced highlights of clinical data presented during the Digestive Disease Week 2009 conference (“DDW”). The abstract has also been accepted for publication in *Gastroenterology*, the official journal of the American Gastrointestinal Association Institute.

The study’s results were presented by its Principal Investigator, Jerome D. Waye, MD, as part of the American Gastroenterological Association (AGA) Foundation’s Late-Breaking Abstract Forum. Titled “Effectiveness of the Third Eye Retroscope for Detecting Polyps in the Right Colon,” the abstract reported on a sub-analysis of the data collected in the company’s 249-patient efficacy study. This study was the basis for the 510(k) clearance granted for the Third Eye Retroscope in February 2009.

The sub-analysis showed that using the Third Eye Retroscope with a standard colonoscope increased the detection of all polyps by 16.5% on the right side of the colon and 9.7% on the left side of the colon, relative to the colonoscope alone. In the population studied, there was a 14.9% increase in the adenoma detection rate on the right side and a 4.1% increased adenoma detection rate on the left side with the use of the Third Eye Retroscope. All of these increased detection rates were statistically significant. Mean withdrawal time was 10.9 minutes.

“On average, we found 13.2% more polyps using the Third Eye Retroscope, which is both statistically and clinically significant. In response to the recent Canadian study suggesting that colonoscopy may offer less protection against cancer in the right colon than previously thought, we looked at additional detection rates by the Third Eye Retroscope in the right colon. We found that the improvement with the Third Eye Retroscope compared to the colonoscope alone was statistically significant in both sides of the colon,”

Avantis Medical Announces Clinical Data

said Dr. Wayne. “These data have a very real impact on patients, who benefit when we find polyps with the Third Eye Retroscope that might otherwise have been missed during colonoscopy.”

“Extensive independent research has shown that lesions can be missed during standard colonoscopy if they are located behind one of the many folds in the wall of the colon. This study showed that, when used with a standard colonoscope, the Third Eye Retroscope is highly effective in detecting additional lesions in the right side of the colon, where the need for improvement may be greatest,” said Jack Higgins, MD, Chief Medical Officer of Avantis Medical. “This is especially exciting because the Third Eye Retroscope is the only new technology that has rigorous clinical data demonstrating a positive impact on detection rates for colonoscopy.”

About DDW

DDW is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases, the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy and the Society for Surgery of the Alimentary Tract, DDW takes place May 30 – June 4, 2009, at the McCormick Place, Chicago, IL. The meeting showcases approximately 5,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. For more information, visit www.ddw.org.

About the Third Eye® Retroscope® and Avantis Medical Systems, Inc.

Avantis Medical Systems, Inc. markets the Third Eye Retroscope, an FDA-cleared, disposable, catheter-based camera indicated for use with a standard colonoscope to provide an additional view of the colon for diagnostic and detection purposes. Deployed through the instrument channel of a standard colonoscope, the Third Eye provides the physician with a backward view to complement the colonoscope’s forward view of the lining of the colon. The device is commercially available to physicians who perform colonoscopies.

The Third Eye is the only technology cleared by the FDA to enhance polyp detection when used in conjunction with colonoscopy. Although colonoscopy is the gold standard for preventing colon cancer by finding and removing polyps and other lesions, clinical literature documents that up to approximately 12-24% of polyps can be missed during examination.^{1 2 3} The Third Eye has been shown in clinical studies to help physicians find 13.2% more polyps than a colonoscope alone.⁴

Avantis Medical is focused on delivering cost effective solutions for improved detection and prevention of cancers of the gastrointestinal tract. The company has an extensive portfolio of patents covering innovative devices based on the convergent technologies of micro-chips, enhanced video processing and catheter based delivery systems. For more information, visit www.AvantisMedical.com or www.ThirdEyeRetroscope.com.

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¹ Pickhardt, P.J.; Nugent, P.A.; Mysliwiec, P.A.; et al. Location of adenomas missed by optical colonoscopy. *Annals of Internal Medicine* 141(5):352-360, 2004.

² Pabby, A.; Schoen, R.E.; Weissfeld, J.L.; et al. Analysis of colorectal cancer occurrence during surveillance colonoscopy in the dietary Polyp Prevention Trial. *Gastrointestinal Endoscopy* 61(3):385-391.

³ Rex, D.K.; Cutler, C.S.; Lemmel, G.T.; et al. Colonoscopic miss rates of adenomas determined by back-to-back colonoscopies. *Gastroenterology* 112(1):24-28, 1997.

⁴ Wayne, J.D.; Rex, D.K.; et al. The Third Eye Retroscope Auxiliary Endoscopy System Improves Detection of Polyps in the Colon – A Prospective Efficacy Evaluation. *Endoscopy Supplement No. I(40): A24, OP1111, 2008.*