# For Immediate Release

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## NinePoint Medical Announces Publication of 1000 Patient Registry Study

**Bedford, Mass. – May 9, 2019 –** NinePoint Medical, Inc, a transformative medical device company pioneering the use of Optical Coherence Tomography (OCT) for gastrointestinal applications, today announced the publication of their 1000 patient Volumetric Laser Endomicroscopy (VLE) Registry study focused on Barrett's Esophagus. The 18 site study, published in Diseases of the Esophagus, enrolled 1000 patients between 2014 and 2016 for imaging using the NvisionVLE® Imaging System.

The study was designed to determine usage patterns of VLE in clinical practice and to estimate quantitative and qualitative performance metrics, with this publication focused on Barrett's Esophagus. All enrolled patients were examined with standard upper endoscopy, followed by the use of VLE to identify focal areas of concern for targeted biopsy. Across the Barrett's Esophagus patient population, inclusion of VLE imaging to the endoscopy procedure increased neoplasia (high grade dysplasia and cancer) detection by 55% beyond the standard of care. In a treatment naïve cohort of patients with no concerning findings on endoscopy, biopsies based only on VLE findings identified 700% more neoplasia than random biopsies of the Barrett's Esophagus segment, the current standard of care. Overall, study investigators reported that VLE improved the Barrett's Esophagus management process when used as a tool for targeting biopsies and guiding treatment.

"I personally have seen VLE improve neoplasia detection in my own Barrett's Esophagus patients, but it is great to see that impact demonstrated in this large prospective multi-center study," stated Michael S. Smith, MD, MBA, Chief of Gastroenterology and Hepatology at Mount Sinai West and Mount Sinai St. Luke's Hospitals in New York City, and National Principal Investigator of the study. "Esophageal adenocarcinoma incidence continues to grow, and unfortunately continues to inflict poor outcomes on our patients. The ability to identify and treat precursors to this terrible cancer is so important, as it gives us an opportunity to prevent it from even appearing in the first place. Conventional imaging modalities and random biopsies fail to identify neoplasia in many patients. VLE's ability to improve detection of these lesions allows us to have a very tangible positive impact on these patients' lives."

"We are very pleased with the outcomes of this study, which are the culmination of hard work by 47 physicians across 18 collaborating hospitals" commented Eman Namati, Ph.D., President and CEO of NinePoint Medical. "What is further encouraging is that this study was undertaken without key technological improvements that have since been launched commercially. We anticipate that future studies using the Real-time Targeting laser marking feature and our newly

launched artificial intelligence software, Intelligent Real-time Image Segmentation, will improve upon these already very positive results. Working together with our commercial partner, Merit Medical, and many of the leading hospitals in the United States, we are ecstatic that this technology continues to have an important and beneficial impact for patients."

The NvisionVLE Imaging System is distributed by Merit Medical Systems, Inc. (NASDAQ:MMSI), and will be exhibited by Merit Medical Endotek at booth #1819 at Digestive Disease Week (DDW) 2019 in San Diego, CA. There are several abstracts to be presented at DDW 2019 using the NvisionVLE Imaging System.

## About the NvisionVLE® Imaging System

The NvisionVLE Imaging System provides a unique and clinically valuable new perspective on esophageal disease - the ability to image within the wall of the esophagus. By providing a high-resolution, real-time scan of the esophagus using Optical Coherence Tomography (OCT) – a technology similar to ultrasound but using infrared light rather than sound waves - the system enables physicians to view structures not evident with conventional imaging, and potentially identify disease that would have otherwise been missed. With the Real-time Targeting$^{TM}$ laser marking feature, physicians can not only locate, but now mark areas of interest for biopsy localization. The newly launched Intelligent Real-time Image Segmentation$^{TM}$ (IRIS) artificial intelligence software colorizes key image features in real time to aid in image review. All of this adds up to potentially improved biopsy targeting, and more complete information to determine the best treatment path for patients.

The NvisionVLE Imaging System has been cleared by the FDA and is commercially available in the U.S. It is indicated for use as an imaging tool in the evaluation of human tissue microstructure, including esophageal tissue microstructure, by providing two-dimensional, cross-sectional, real-time depth visualization and may be used to mark areas of tissue. The software provides segmentation and display of common imaging features, including hyper-reflective surface, layering, and hypo-reflective structures. The NvisionVLE Imaging System is intended to provide an image of tissue microstructure. The safety and efficacy of this device for diagnostic analysis (i.e. differentiating normal versus specific abnormalities) in any tissue microstructure or specific disease has not been evaluated.

## About NinePoint Medical, Inc.

NinePoint Medical is a privately-held medical device company that designs, manufactures, and sells an Optical Coherence Tomography (OCT) imaging platform for clinical use in gastroenterology, pulmonology, urology, gynecology, and ENT, for the evaluation of human tissue microstructure. Using proprietary imaging and software technology, NinePoint Medical is committed to enabling quicker diagnosis of disease and more effective treatments, while reducing the overall cost of healthcare. NinePoint Medical is located in suburban Boston, Massachusetts. For more information, please visit www.ninepointmedical.com.

## About Merit

Founded in 1987, Merit Medical Systems, Inc. is engaged in the development, manufacture and distribution of proprietary disposable medical devices used in interventional, diagnostic and therapeutic procedures, particularly in cardiology, radiology, oncology, critical care and endoscopy. Merit serves client hospitals worldwide with a domestic and international sales force totaling approximately 290 individuals. Merit employs approximately 5,000 people worldwide with facilities in South Jordan, Utah; Pearland, Texas; Richmond, Virginia; Malvern, Pennsylvania; Rockland, Massachusetts; San Jose, California; Maastricht and Venlo, The Netherlands; Paris, France; Galway, Ireland; Beijing, China; Tijuana, Mexico; Joinville, Brazil; Markham, Ontario, Canada; Melbourne, Australia; Tokyo, Japan; and Yishun, Singapore.