



**NEWS RELEASE**

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**NinePoint Medical Announces FDA 510(k) Clearance of a Real-Time Targeting Feature for the NvisionVLE® Imaging System and the First Clinical Cases in the U.S.**

**Bedford, Mass. – May 10<sup>th</sup>, 2016** – NinePoint Medical, Inc., a transformative medical device company pioneering the use of a real-time imaging platform for gastrointestinal applications, announced today that it has received U.S. Food and Drug Administration (FDA) 510(k) clearance to market its Real-time Targeting™ feature for its flagship product, the NvisionVLE® Imaging System. In addition, the first procedures with this new system were performed at Beth Israel Deaconess Medical Center in Boston, Massachusetts.

The NvisionVLE Imaging System employs proprietary Optical Coherence Tomography (OCT) technology allowing physicians to perform a Volumetric Laser Endomicroscopy (VLE) procedure that produces real-time, high-resolution cross-sectional images. This system enables gastroenterologists to evaluate tissue for potential disease that may not be visible with conventional medical imaging technologies such as endoscopy and ultrasound.

The NvisionVLE Imaging System was launched in the U.S. in late 2013. To date, over 5,000 VLE procedures have been performed at leading hospitals in the U.S. The addition of this Real-time Targeting feature allows physicians to not only locate, but now to mark areas of interest. This marking feature, in combination with an improved workflow, enables more accurate targeting, potentially leading to improved diagnosis and more effective therapeutic treatment options for patients.

“OCT imaging has become an integral part of the care of my patients with esophageal disease,” stated Dr. Douglas K. Pleskow, MD, Beth Israel Deaconess Medical Center, Associate Clinical Professor of Medicine, Harvard Medical School. “The addition of Real-time Targeting will streamline the procedure and provide me with more confidence when targeting esophageal tissue for biopsy or treatment.”

“Today’s announcement represents the successful culmination of a four-year effort by the NinePoint Medical team and our advisors to bring this significant targeting feature for our OCT-based imaging platform to the U.S. market,” commented Christopher R. von Jako, Ph.D., President and CEO, NinePoint Medical, Inc. “We are currently conducting a controlled-market release at a few select U.S. hospitals, and look forward to making the feature more broadly available to our customers later in 2016.”

### **About the NvisionVLE® Imaging System**

The NvisionVLE Imaging System provides a unique and clinically valuable new perspective of 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 recent addition of a Real-time Targeting feature, physicians can not only locate, but now mark areas of interest. This marking feature, in combination with an improved workflow, enables more accurate targeting, potentially leading to improved diagnosis and more effective therapeutic decisions for patients. The NvisionVLE® Imaging System has been cleared by the FDA and is commercially available in the U.S.

### **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, the Company 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](http://www.ninepointmedical.com).