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CSA Medical Announces Expansion of truFreeze® Label to Include Barrett's Esophagus with High Grade Dysplasia

Boston, MA – May 30, 2017: CSA Medical announced on Thursday, the expansion of its truFreeze® label to refer specifically to Barrett's Esophagus with high grade dysplasia. This expansion comes after 510(k) submission of clinical data supporting the use of truFreeze Spray Cryotherapy in patients with Barrett's Esophagus.

Barrett's Esophagus is a complication of Gastro Esophageal Reflux Disease (GERD) in which the tissue lining the esophagus changes form due to the presence of stomach acid on the tissue over time. In high grade dysplasia, this change in tissue has progressed to the formation of pre-cancerous cells, and intervention is recommended. It is estimated that 0.5 – 2.0% of adults have Barrett's Esophagus¹.

“Barrett's esophagus with high grade dysplasia carries an extremely high risk of progressing to adenocarcinoma of the esophagus, a highly fatal condition. Endoscopic ablation is now the standard of care for treating this condition and preventing cancer,” said Bruce Greenwald, MD, Professor of Medicine, Division of Gastroenterology and Hepatology at University of Maryland School of Medicine. “I have been treating patients with Barrett's esophagus for over 25 years and using liquid nitrogen spray cryotherapy since 2006. truFreeze spray cryotherapy, utilizing liquid nitrogen at -196° C, provides a truly effective treatment for elimination of Barrett's esophagus with minimal to no pain.”

“We are pleased to have obtained FDA clearance to expand our indications for use to include specifically Barrett's Esophagus with high grade dysplasia as an example of benign disease ablation as well as our present indication for malignant disease ablation. The data set that formed the basis of this claim came from our prospective post market registry that delineated ablation using truFreeze spray cryotherapy as specified in our instructions for use. Achieving a CE-D rate of 87% in this patient cohort is in keeping with numerous previously published truFreeze reports,” says Ellen Sheets MD, CEO and President of CSA Medical.

This label expansion solidifies truFreeze as a treatment option for Barrett's Esophagus, and supports coverage decisions for truFreeze patient treatments.

About CSA Medical

CSA Medical, Inc. develops and manufactures a proprietary interventional spray cryotherapy technology platform utilizing unique properties of liquid nitrogen spray delivered by a software driven

¹ Runge, T, et al, Epidemiology of Barrett's Esophagus and Esophageal Adenocarcinoma, [Gastroenterol Clin North Am.](#) 2015 Jun; 44(2): 203-31.

device with specialty catheters that enable delivery of spray cryogen inside the body to flash freeze and destroy unwanted tissue allowing for a rejuvenative pattern of healing. CSA manufactures and distributes this technology in the USA as the truFreeze® system which is currently used to ablate benign (e.g. Barrett's Esophagus with high grade dysplasia) and malignant lesions.

To learn more about our technology, please visit <http://csamedical.com/>.

truFreeze is a registered trademark of CSA Medical, Inc.

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