Hatch Medical Retained by ADN International to Secure Commercialization Partner for Strome-Blitzer™ Cytologic Collection Balloon

Santa Rosa Beach, Florida – Medical device incubator and technology brokerage firm, Hatch Medical, L.L.C. (www.hatchmedical.com) announced recently that it has entered into an exclusive brokerage relationship with ADN International (https://www.aero-di-namics.com/) and renowned physician inventors, Marshall Strome, MD and Andrew Blitzer, MD, DDS. Hatch Medical will be representing their innovative cytologic collection balloon to assist in screening patients undergoing routine esophagoscopy who are at risk for distal esophageal disease.

After eight years in development, the Strome-Blitzer™ balloon platform received FDA 510K clearance in June of 2019. Designed to meet the Seattle protocol recommendation of four quadrant sampling, applied to a cytology technique, with an easy to use one time device, proof of concept was established in large animal trials in comparison to the gold standard of brush biopsy. The Strome-Blitzer™ balloon was shown to capture substantially more cells than standard brush biopsy cytology in a swine model, and in a single pass, as opposed to multiple passes for a cytology brush.

An early 2021 human trial conducted by gastroenterologists at Vanderbilt University compiled data from ten patients and was designed to evaluate the clinical utility of the product as well as the clinical relevance of the sampling. The study revealed that the Strome-Blitzer™ balloon showed excellent sampling of the distal esophageal mucosa on all measures with minimal background material collected.

A cytology collection system is a medical device used to collect cells from patients undergoing upper endoscopy and who are believed to be at risk for esophageal cancer. Based upon recently released market data, approximately 10MM upper endoscopies are performed each year, many with cytology or biopsy and growing at 6% annually. It has been estimated that over 16,080 deaths occur annually from esophageal cancer (13,020 in men and 3,060 in women), and the lifetime risk of esophageal cancer in the United States is approximately one in 132 in men and about one in 455 in women. Similar rates are found in western Europe and even higher rates in China.

The Strome-Blitzer™ Cytology Balloon is an inflatable biopsy platform consisting of a catheter with a silicone balloon at its distal end. The balloon has six collection pleats on its surface, and each pleat houses two cytology strips for specimen collection. While the balloon is uninflated, the strips are covered by the balloon pleats, however, the collection strips become exposed when inflated enabling the circumferential collection of esophageal cells. The balloon is inflated and deflated with the use of a syringe and attached catheter, and is a sterile, single-use device. Additionally, there are four location indicator markings on the proximal balloon surface for orientation during esophagoscopy.

We are thrilled to be working with Drs. Strome and Blitzer to help bring this exciting technology to the market," said Steve Hvozda, Principal of Hatch Medical. "The Strome-Blitzer™ Cytology

Balloon product line is available to interested parties via a technology license or acquisition through an exclusive agreement with Hatch Medical," added Mr. Hvozda.

Charles S. Carignan, MD, Consulting CEO of ADN International commented, "We are delighted to have Hatch Medical as our exclusive broker and look forward to identifying a commercial partner committed to bringing our advanced cytologic balloon sampling products to market."

Hatch Medical jointly develops and brokers minimally invasive medical devices through its network of risk-sharing partners. For additional information on this, or other Hatch Medical, L.L.C. products and services, visit https://www.hatchmedical.com/contact-us/ to contact the company. This release and additional news can be obtained by visiting Hatch Medical's web site: www.hatchmedical.com.

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