

Motus GI Receives FDA Clearance to Market Pure-Vu® Slim Sleeve for Use with Slim Colonoscopes

- Pure-Vu® Slim Sleeve provides broader procedural access to cover a full range of colonoscopes
- Pure-Vu® Slim Sleeve has the same effective cleansing capabilities and has demonstrated enhanced navigation performance in usability testing

FORT LAUDERDALE, Fla.--(BUSINESS WIRE)-- [Motus GI Holdings, Inc.](#), (NASDAQ:MOTS) ("Motus GI" or the "Company"), a medical technology company dedicated to improving clinical outcomes and enhancing the cost-efficiency of colonoscopy, announced today that it has received special 510(k) clearance from the U.S. Food and Drug Administration (FDA) for Pure-Vu® Slim Sleeve, a compatible extension to the Pure-Vu® System for slim colonoscopes.

The Pure-Vu® Slim Sleeve design enables Motus GI to now gain access to the full range of procedures in the colonoscopy market as we estimate, through consultation with colonoscope manufacturing companies, approximately 30% of procedures are performed with a slim colonoscope. Pure-Vu® Slim Sleeve has the same cleansing performance as the standard Pure-Vu® Sleeve and both versions work with the same Pure-Vu® workstation control system. The Pure-Vu® Slim Sleeve has been designed to be compatible with smaller diameter and more flexible slim colonoscopes with additional enhancements to the Company's low friction lubricious coating technology to aid in navigation through the colon.

"Having Pure-Vu® compatible with slim colonoscopes will be critically important for patients with complex anatomy which can happen quite often in the inpatient setting," noted Tamas Gonda, M.D. from Columbia University Medical Center in NY. "From my *in vitro* testing experience with the Pure-Vu® Slim Sleeve on a slim colonoscope, the device had excellent handling and navigation performance."

[Mark Pomeranz, CEO of Motus GI](#), commented, "Receiving this special 510(k) clearance from the FDA for the Pure-Vu® Slim Sleeve is an important milestone that will allow physicians to use the Pure-Vu® System on slim colonoscopes which we estimate, through consultation with colonoscope manufacturing companies, are currently used in approximately 30% of procedures and growing in the United States. Pure-Vu® Slim Sleeve was designed with the same stringent standards used for the Pure-Vu® System. We are excited to have this new product available for clinical use in the coming weeks. We expect that it will increase the number of patients that can benefit from the Pure-Vu® System, which we believe has the ability to rapidly cleanse the colon and overcome the high rates of insufficient bowel prep in the inpatient setting that can lead to delayed diagnosis, repeat preps and procedures, as well as longer hospital stays."

"We remain focused on our post-approval clinical trials and market development programs with leading U.S. hospitals that are utilizing the Pure-Vu® System on a pilot basis, or in clinical trials such as the ongoing REDUCE study and our upcoming EXPEDITE study, in preparation for our 2019 commercial launch. We are establishing strong working relationships with physician champions and their staff within leading institutions that we believe can become long-term important customers for our products. We look forward to further advancing the development and adoption of both the Pure-Vu® System and Pure-Vu® Slim Sleeve, which we believe will improve quality of care and reduce healthcare costs by reliably and predictably moving patients through the hospital system to a successful examination," added Mr. Pomeranz.

Pure-Vu® generates a proprietary pulsed vortex™ mixture of water and air to safely remove debris from the colon mucosa while simultaneously evacuating the bowel contents, clearing the way for the endoscopist to perform a quality examination even when the patient does not or is not able to complete a successful prep on his or her own. The Pure-Vu® System consists of a disposable component and a workstation controller. The disposable, now available in standard and slim versions, fits over a colonoscope without interfering with the working channel. Motus GI's clinical trials, such as the ongoing REDUCE study and its upcoming EXPEDITE study, are designed to evaluate the Pure-Vu® System's ability to rapidly cleanse the colon intra-procedurally to allow physicians to better visualize, diagnose and, if necessary, treat the colon using standard techniques and tools.

About Motus GI and the Pure-Vu® System

Motus GI Holdings, Inc. is a medical technology company, with subsidiaries in the U.S. and Israel, dedicated to improving clinical outcomes and enhancing the cost-efficiency of colonoscopy. The Company's flagship product is the Pure-Vu® System, a 510(k) U.S. Food and Drug Administration cleared medical device indicated to help facilitate the cleaning of a poorly prepared colon during the colonoscopy procedure. The device integrates with standard colonoscopes to enable cleaning during the procedure while preserving standard procedural workflow and techniques. The Pure-Vu® System has received CE mark approval in Europe. The Pure-Vu® System is currently being introduced on a pilot basis in the U.S. market, and the Company is planning to initiate a full commercial launch focused on the inpatient colonoscopy market in the U.S. and select international markets in 2019.

Challenges with bowel preparation for inpatient colonoscopy represent a significant area of unmet need that directly affects clinical outcomes and increases the cost of care in a market segment that comprises approximately 1.5 million annual procedures in the U.S. and approximately 4 million annual procedures worldwide. Published studies have found that the inpatient population experiences rates of insufficiently prepped colons at the time of colonoscopy as high as 55%. This has been shown to lead directly to significantly longer hospital stays and other additional costs due to the need for repeated preps, repeated colonoscopies and additional diagnostic procedures. This is exemplified in a recently published study from Northwestern University Hospital System which showed an average hospital stay extension of two days and cost increase of as much as \$8,000 per patient as a result of challenges associated with bowel preparation. Motus GI believes the Pure-Vu® System may improve outcomes and lower costs for hospitals by reducing the time to successful colonoscopy, minimizing delayed and aborted procedures, and improving the quality of an exam. In clinical studies to date, the Pure-Vu® System significantly increased

the number of patients with an adequate cleansing level, according to the Boston Bowel Preparation Scale Score, a validated assessment instrument.

For more information, visit www.motusgi.com and connect with the Company on [Twitter](#), [LinkedIn](#), [Facebook](#) and [Google+](#).

Forward-Looking Statements

This press release contains certain forward-looking statements. Forward-looking statements are based on the Company's current expectations and assumptions. The Private Securities Litigation Reform Act of 1995 provides a safe-harbor for forward-looking statements. These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms, including without limitation, risks inherent in the development and commercialization of potential products, uncertainty in the timing and results of clinical trials or regulatory approvals, maintenance of intellectual property rights or other risks discussed in the Company's Form 10-K filed on March 28, 2018, and its other filings with the Securities and Exchange Commission. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date hereof. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

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