TransEnterix Announces Submission of 510(k) to FDA for First Machine Vision System in Robotic Surgery

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New Technology Would Enable Augmented Intelligence with the Senhance Surgical System

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)--Jan. 14, 2020-- TransEnterix, Inc. (NYSE American: TRXC), a medical device company that is digitizing the interface between the surgeon and the patient to improve minimally invasive surgery, today announced the Company filed a 510(k) submission with an Intelligent Surgical Unit (ISU™)[1] that is designed to enable machine vision capabilities on the Senhance® Surgical System.

“TransEnterix is the first company to seek FDA clearance for machine vision technology in abdominal robotic surgery. Rather than simply passing a video signal to the surgeon, the Intelligent Surgical Unit for Senhance will initially have the ability to actually visualize the surgical field to guide movement and capture information,” said Anthony Fernando, TransEnterix president and CEO. “This technology advance is an important first step towards enabling augmented intelligence and we believe it will support continued machine vision driven advances in surgery performed with the Senhance Digital Laparoscopy Platform."

The initial features of the Intelligent Surgical Unit (ISU) are designed to increase control in visualization beyond what has previously been available in digital laparoscopy or robotic surgery. The cleared Senhance System already features unique eye-tracking camera control and the new technology would enable machine vision driven control of the camera for a surgeon by responding to commands and recognizing certain objects and locations in the surgical field. The ISU hardware is also designed to be compatible with planned future augmented intelligence features such as scene cognition and surgical image analytics that are expected to continue to drive meaningful innovations in digital laparoscopy with Senhance.

“Many of us that perform and teach surgery firmly believe that the care of patients will be transformed by augmented intelligence and machine vision capabilities in the future,” said Dr. Amit Trivedi, chair of surgery at Hackensack Meridian Health Pascack Valley Medical Center and a participant in the design and usability studies conducted in support of the 510(k) submission of the ISU. “Imagine if a computer could be the best assistant you’ve ever had in surgery by anticipating and moving a camera effortlessly to maximize control of the visual field. I’m very excited about this new addition to the Senhance System.”

This Intelligent Surgical Unit will be compatible with the global installed base of Senhance Surgical Systems, and will be compatible with third-party vision systems that are currently supported by Senhance.

Senhance Indication for use

In the U.S., The Senhance® Surgical System is intended to assist in the accurate control of laparoscopic instruments for visualization and endoscopic manipulation of tissue including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, mobilization and retraction. The Senhance Surgical System is intended for use in laparoscopic gynecological surgery, colorectal surgery, cholecystectomy, and inguinal hernia repair. The system is indicated for adult use. It is intended for use by trained physicians in an operating room environment in accordance with the Instructions for Use. The device is restricted to sale by or on the order of a physician.

About TransEnterix

TransEnterix is a medical device company that is digitizing the interface between the surgeon and the patient to improve minimally invasive surgery by addressing the clinical and economic challenges associated with current laparoscopic and robotic options in today's value-based healthcare environment. The Company is focused on the commercialization of the Senhance System, which digitizes laparoscopic minimally invasive surgery. The system allows for robotic precision, haptic feedback, surgeon camera control via eye sensing and improved ergonomics while offering responsible economics. The Senhance System is available for sale in the US, the EU, Japan and select other countries. For more information, visit www.transenterix.com.

Forward-Looking Statements

This press release includes statements relating to the Senhance System and the Company’s 510(k) submission with an Intelligent Surgical Unit that is designed to enable machine vision capabilities on the Senhance Surgical System. These statements and other statements regarding our future plans and goals constitute "forward looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, and are intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. Such statements are subject to risks and uncertainties that are often difficult to predict, are beyond our control and which may cause results to differ materially from expectations and include whether the FDA will clear TransEnterix’s 510(k) submission; whether the 510(k) submission will support continued machine vision driven advances in surgery performed with the Senhance Digital Laparoscopy Platform; and whether the ISU hardware with planned future augmented intelligence features will continue to drive meaningful innovations in digital laparoscopy with Senhance. For a discussion of the risks and uncertainties associated with TransEnterix's business, please review our filings with the Securities and Exchange Commission (SEC), including our Annual Report on Form 10-K for the year ended December 31, 2018, filed with the SEC on February 27, 2019 and our other filings we make with the SEC. You are cautioned not to place undue reliance on these forward looking statements, which are based on our expectations as of the date of this press release and speak only as of the origination date of this press release. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

[1]Pending 510(k), not available for sale within the United States.

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