

TransEnterix Announces Submission of General Surgery Expansion in the US

August 4, 2020

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)--Aug. 4, 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 that it has submitted an indications filing to the FDA to expand General Surgery usage of the Senhance Surgical System.

"This submission is an important milestone for the continued application of Senhance in the highest volume and value procedures," said Anthony Fernando, president and chief executive officer at TransEnterix. "General Surgery is by far the largest procedural area in minimally invasive abdominal surgery, and we are pleased to have submitted significant additional clinical data to expand the procedures for which surgeons can utilize the benefit of Senhance."

The Senhance System is the first and only digital laparoscopic surgical platform designed to maintain laparoscopic MIS standards while providing digital benefits such as haptic feedback, robotic precision, comfortable ergonomics, advanced instrumentation including, 3 mm mini-laparoscopic instruments, eye sensing camera control and reusable standard instruments to help maintain per-procedure costs similar to traditional laparoscopy. The Senhance System is also the first machine-vision system in robotic surgery which is powered by the new intelligent Surgical Unit (ISU) that enables augmented intelligence in surgery.

Current Senhance US Indication for Use

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.

About TransEnterix

At TransEnterix, Inc., we are digitizing the interface between the surgeon and the patient to improve minimally invasive surgery (MIS) through a new category of care called Digital Laparoscopy. Digitizing the interface enables the use of advanced capabilities like augmented intelligence, connectivity and robotics in laparoscopy, and allows us to address the current clinical, cognitive and economic shortcomings in surgery. The system features the first machine vision system for use in robotic surgery which is powered by the new intelligent Surgical Unit (ISU) that enables augmented intelligence in surgery. The Senhance® Surgical System brings the benefits of Digital Laparoscopy to patients around the world while staying true to the principles of value-based healthcare. Learn more about Digital Laparoscopy with the Senhance Surgical System here: https://senhance.com/. Now available for sale in the US, the EU, Japan, and select other countries. For a complete list of indications for use, please visit: https://www.transenterix.com (indications-for-use/.

Forward-Looking Statements

This press release includes statements relating to the Senhance System and the Company's submission of an indication filing to the FDA to expand General Surgery usage of 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 the filing to expand the General Surgery indication usage of the Senhance Surgical System. 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, 2019, filed with the SEC on March 16, 2020 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.

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