TransEnterix Receives FDA 510(k) Clearance for Senhance Ultrasonic System

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Senhance Ultrasonic advanced energy capability broadens potential applicability of Senhance surgery in the United States

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)--Jan. 15, 2019-- TransEnterix, Inc. (NYSE American:TRXC), a medical device company that is digitizing the interface between surgeons and patients to improve minimally invasive surgery, today announced the Company received FDA 510(k) clearance for its Senhance™ Ultrasonic System.

“Advanced energy devices are used within a high percentage of cases across a wide range of procedures, which make them a critical tool for laparoscopic surgeons,” said Todd M. Pope, TransEnterix president and CEO. “We believe the addition of the Senhance Ultrasonic System is significant and broadens the attractiveness of the Senhance platform and digital laparoscopy for surgeons in the U.S.”

Advanced energy devices, including ultrasonic devices, represent some of the most versatile and critical tools for surgeons in minimally invasive surgery. These instruments deliver controlled energy to effectively ligate and divide tissue, and minimize thermal injury to surrounding structures. The Company’s Senhance Ultrasonic System is now available in the U.S., as well as all countries that accept a CE Mark.

“The addition of ultrasonic technology is a significant expansion of the Senhance system capability preferred by many surgeons during complex procedures,” said Dr. Steven D. McCarus, MD, FACOG, Chief of Gynecologic Surgery at Florida Hospital Celebration Health. “Combining advanced energy tools with the precision, control, haptics and ergonomics of the Senhance digital interface may allow many surgeons to confidently use this technology across the broadest range of pathology and patients.”

The Senhance™ System is the first new abdominal robotic surgery platform to receive FDA clearance since 2000, and is the first and only digital laparoscopic surgical platform to offer the security of haptic force feedback that allows surgeons to feel the forces the instruments generate when handling delicate tissue. It is also the first robotic surgical system to offer reusable instruments that help keep per-procedure costs similar to that of traditional laparoscopic surgeries, as well as 3 mm instruments for microlaparoscopic procedures that enable virtually scarless incisions for patients. These advanced technologies exclusive to Senhance were designed to pave the way to the future of robotic surgery by improving the patient and surgeon experience, while helping to lower per-procedure costs and ultimately healthcare costs in general for hospitals and patients.

In the U.S. the Senhance System is cleared for laparoscopic colorectal, gynecological, inguinal hernia and cholecystectomy (gallbladder removal) surgery.

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 Surgical 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 Surgical System is available for sale in the US, the EU and select other countries. For more information, visit www.transenterix.com.

Forward-Looking Statements

This press release includes statements relating to the Senhance™ Surgical System and the Senhance Ultrasonic System and our current regulatory and commercialization plans for this product. 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 Senhance Ultrasonic advanced energy capability will broaden potential applicability of Senhance surgery in the United States, whether the Senhance Ultrasonic System broadens the attractiveness of the Senhance platform and digital laparoscopy for surgeons in the U.S., and whether combining advanced energy tools with the precision, control, haptics and ergonomics of the Senhance digital interface will allow surgeons to confidently use the technology across the broadest range of pathology and patients. 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 filed on March 8, 2018 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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