TransEnterix Receives FDA 510(k) Clearance for 3mm Diameter Instruments

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Receives FDA 510(k) clearance for 3mm instrument set as well as additional 5mm instruments, advancing minimally invasive capabilities within digital laparoscopy

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)--Oct. 11, 2018-- 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 the Company received FDA 510(k) clearance for 3 millimeter diameter instruments, as well as additional 5 millimeter Senhance System instruments.

The clearance of the 3 millimeter diameter instruments will allow the Senhance to be used for microlaparoscopic surgeries, enabling surgeons to operate through tiny incisions considered virtually scarless for patients.

“The ability to perform microlaparoscopic procedures using 3 millimeter instruments represents an unparalleled shift in the world of robotic surgery and a capability exclusive to the Senhance system,” said Todd M. Pope, TransEnterix CEO. “The addition of 3 millimeter instruments will allow many high volume surgeries to be performed with smaller incisions, which supports our mission of advancing minimally invasive surgical capabilities within digital laparoscopy.”

“Utilizing 3 millimeter micro instruments on a robotic system represents a new advancement in reducing the invasiveness of many surgeries,” said Dr. Steven D. McCarus, MD, FACOG, Chief of Gynecologic Surgery at Florida Hospital Celebration Health. “Patients find such small incisions to be virtually scarless and cosmetically desirable. Surgeons may find that using such tiny instruments with the precision and control of a digital interface makes microlaparoscopy a preferred option to treat more conditions.”

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 related instruments 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 ability to perform microlaparoscopic procedures using 3 millimeter instruments represents an unparalleled shift in the world of robotic surgery; whether the addition of 3 millimeter instruments will allow many high volume surgeries to be performed with smaller incisions and whether surgeons may find that using tiny instruments with the precision and control of a digital interface makes microlaparoscopy a preferred option to treat more conditions.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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