TransEnterix Announces CE Mark Approval for Pediatric Indication for Senhance Surgical System

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TransEnterix is First to Offer Robotic 3 mm Microlaparoscopic Surgery for Pediatric Patients

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)--Feb. 12, 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 the Company received CE Mark approval for an expanded indication to treat pediatric patients above 10kg (approximately 22 lbs) with the Senhance® System.

“Given the size of the patients, pediatric surgery seeks to use the smallest instruments and scopes possible to minimize invasiveness, yet it is critical to maintain a high degree of precision,” said Anthony Fernando, president and chief executive officer of TransEnterix. “The Senhance System is designed to maximize control of instruments as small as 3 mm and be compatible with small scopes while also retaining the sense of touch through haptic feedback. This makes our technology uniquely positioned to meet the requirements of pediatric surgeons, and we look forward to working closely with leading European hospitals to serve the needs of their pediatric patients.”

“The ability to use 3 mm microlaparoscopic instruments on a robotic platform is very exciting and is a large step forward in treating pediatric patients,” said Prof. Dr. Wim van Gemert, chairman of the department of pediatric surgery, Maastricht University Medical Center+ in the Netherlands. “Especially in younger patients, smaller ports and instruments are critically important in achieving the best outcomes given the body size constraints in these patients.”

The Senhance® Surgical System is the first and only digital laparoscopic platform designed to maintain laparoscopic MIS standards while providing digital benefits such as haptic feedback, robotic precision, eye-sensing camera control, comfortable ergonomics, advanced instrumentation including, 3 mm microlaparoscopic instruments, eye-sensing camera control and reusable standard instruments to help maintaining per-procedure costs similar to traditional laparoscopy.

Senhance European Indication for Use

The Senhance® Surgical System has received a CE Mark according to the Medical Device Directive and is intended to be used for laparoscopic surgery in the abdomen, pelvis and limited uses in the thoracic cavity excluding the heart and greater vessels. The system is indicated for adult and pediatric use in CE marked territories.

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, 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 expansion of indications to include pediatric applications in CE marked territories. 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, including whether the indication expansion to treat pediatric patients will broaden our Senhance footprint in CE countries and whether the Senhance System technology is uniquely positioned to meet the requirement of pediatric surgeons. 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.

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