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TransEnterix, Inc. Provides Update on SurgiBot FDA 510(k) Submission Process

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)-- TransEnterix, Inc. (NYSE MKT: TRXC), a medical device company that is pioneering the use of robotics to improve minimally invasive surgery, today announced that the Company has received an update from the FDA on the status of the 510(k) submission for the SurgiBot™ System.

The FDA advised the Company that it has not yet concluded the review of the Company's 510(k) submission and provided an update on the status of the filing. The Company has updated its timing expectations and now expects to receive a decision from the FDA by mid-April, 2016. The Company previously expected a decision from the FDA in the first quarter of 2016.

"We have been engaged in constructive dialogue with the FDA throughout the entire submission process," said Todd M. Pope, President and Chief Executive Officer of TransEnterix. "We appreciate the proactive exchange with the FDA and look forward to their decision, and continue to expect clearance for the SurgiBot."

About TransEnterix

TransEnterix is a medical device company that is pioneering the use of robotics to improve minimally invasive surgery by addressing the clinical and economic challenges associated with current laparoscopic and robotic options. The company is focused on the development and commercialization of the SurgiBot™ System, a single-port, robotically enhanced laparoscopic surgical platform, and the commercialization of ALF-X®, a multi-port robotic system that brings the advantages of robotic surgery to patients while enabling surgeons with innovative technology such as haptic feedback and eye tracking camera control. The SurgiBot System is not yet available for sale in any market. The ALF-X has been granted a CE Mark but is not available for sale in the US. For more information, visit the TransEnterix website at www.transenterix.com.

Forward Looking Statements

This press release includes statements relating to the ALF-X® System, the SurgiBot™ System and our current regulatory and commercialization plans for these products. 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 we will obtain SurgiBot clearance, if at all, from the FDA by mid-April 2016; and whether we will be able to successfully commercialize the SurgiBot System and the ALF-X 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 filed on March 3, 2016 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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