



Asensus Surgical Receives FDA 510(k) Clearance For Pediatric Indication for Senhance Surgical System

March 20, 2023

Senhance Offers the First and Only Digital Laparoscopic Surgery Solution for Pediatric Patients

RESEARCH TRIANGLE PARK, N.C., March 20, 2023 (GLOBE NEWSWIRE) -- Asensus Surgical, Inc. (NYSE American: ASXC), a medical device company that is digitizing the interface between the surgeon and the patient to pioneer a new era of Performance-Guided Surgery™ (PGS), today announced that it has received 510(k) clearance from the FDA for an expanded indication to treat pediatric patients with the Senhance® System. The Senhance System is already approved for pediatric patients in the EU and Japan.

With the combination of 3mm instrumentation, 5mm camera scope, haptic feedback, and advanced clinical intelligence provided by the Intelligent Surgical Unit™, the Company believes that the Senhance System is uniquely positioned to bring the benefits of surgical robotics to pediatric patients in a way that no other platform on the market can, by offering a unique and unmatched reduction in invasiveness on a robotic platform. We have seen strong early clinical utilization in Europe, with surgeons having successfully performed pediatric general, upper GI, colorectal and urologic procedures using the Senhance System.

"We are excited to bring the benefits of surgical robotic technology to the underserved pediatric patient population in the United States. Given the small size of the patients, pediatric surgery seeks to use the least invasive instruments and scopes, while maintaining a high level of precision and stability. The Senhance System is uniquely qualified to meet these needs of pediatric surgeons," said Anthony Fernando, Asensus Surgical President and CEO. "We look forward to bringing all of our learnings from over three years of performing pediatric procedures in Europe and Japan to the US."

Dr. Thom Lobe, Pediatric Surgeon at the Sinai Health System in Chicago said, "The Senhance System is the perfect robotic platform for use in pediatric patients. No other robotic system uses reusable 3mm instruments suitable for smaller patients. For those familiar with laparoscopic surgery, the system is easy to learn and has several advantages including economical value, a camera system controlled by the surgeon's eyes, and improved safety features such as haptic feedback."

The Senhance System is now indicated to perform pediatric procedures in the U.S., Europe, and Japan. Refer to <https://www.senhance.com/indications> for the full indications for use statements.

About Asensus Surgical, Inc.

Asensus Surgical, Inc. is digitizing the interface between the surgeon and patient to pioneer a new era of Performance-Guided Surgery by unlocking clinical intelligence for surgeons to enable consistently superior outcomes and a new standard of surgery. Based upon the foundations of Digital Laparoscopy and the Senhance Surgical System, the Company is developing the LUNA™ Surgical System, a next generation robotic and instrument system as a foundation of its Digital Surgery solution. These systems will be powered by the Intelligent Surgical Unit to increase surgeon control and reduce surgical variability. With the addition of machine vision, Augmented Intelligence, and deep learning capabilities throughout the surgical experience, we intend to holistically address the current clinical, cognitive and economic shortcomings that drive surgical outcomes and value-based healthcare. The Senhance Surgical System is now available for sale in the US, EU, Japan, Russia, and select other countries. For a complete list of indications for use, visit: www.senhance.com/indications. To learn more about Performance-Guided Surgery, Digital Laparoscopy with the Senhance Surgical System and the new LUNA System visit www.asensus.com.

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Forward-Looking Statements

This press release includes statements relating to the Senhance Surgical System and the FDA's 510(k) clearance for a pediatric indication for 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 Senhance Surgical System is uniquely positioned to bring the benefits of digital laparoscopy to pediatrics in a way that no other platform on the market can and whether the Senhance Surgical System is the perfect platform for use in pediatric patients. For a discussion of the risks and uncertainties associated with the Company'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, 2022, filed with the SEC on March 2, 2023 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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