

Senzime receives FDA clearance

Press release: Uppsala, October 18, 2019. Senzime AB (publ) today announces that the company's medical technology system for monitoring neuromuscular blockade, TetraGraph, has received 510 (k) clearance by the US drug authority FDA. The clearance gives permission to market and sell TetraGraph in the US market.

"The FDA clearance is a great breakthrough for Senzime allowing us to initiate sales of TetraGraph in the US, the world's largest market. The need for this type of equipment is high and we look forward to being a driving force in reducing anesthesia-related complications," says Pia Renaudin, CEO of Senzime AB.

Senzime is currently in the process of recruiting the head of the US office and establishing a subsidiary. Sales will be both direct and through local distributors with expected first sales in the beginning of 2020.

Over 70 million patients undergo surgery every year using both anesthetic and muscle relaxant drugs and research has shown that over 30 percent suffer from postoperative complications if objective patient monitoring is missing.

TetraGraph is a unique digital system developed to help reduce postoperative complications. It stimulates a peripheral nerve and measures, analyzes and displays real-time muscle function in surgical patients receiving neuromuscular blocking drugs NMBA as part of their general anesthesia.

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TO THE EDITORS

About Senzime

Senzime develops and markets systems, driven by unique algorithms and sensors, to follow patients' nervous systems and electrical impulses – before, during and after surgery. The company's solution is called TetraGraph, a medical technology system that digitally and continuously measures the degree of neuromuscular blockade in the patient. The goal is improved clinical precision and simplified management in healthcare. By preventing complications and enabling healthcare professionals to follow health care guidelines and drug recommendations, TetraGraph contributes to shorter hospitalizations and lower health care costs – in a world where everyone wakes up safely after surgery. The vision is a world without narcotics-related complications. Senzime operates in growing markets that in Europe and the United States are valued in excess of SEK 10 billion. The company's shares are listed on Nasdaq First North Growth Market (ticker SEZI). FNCA Sweden AB, +46 (0)8-528 00 399, info@fnca.se, is Certified Adviser for Senzime. www.senzime.com

This information is insider information that Senzime AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication through the agency of the contact person set out above, on October 18, 2019, 22.00.