Senzime submits 510 (k) application to the FDA

Uppsala, September 25, 2017. Senzime AB (publ) announced today that the company has submitted a 510 (k) application to the US Food and Drug Administration (FDA) for approval of the TetraGraph in the United States.

This FDA application is part of Senzime's launch plan for the TetraGraph, with primary focus of launching in Europe, Japan and the United States - central markets for monitoring patients undergoing surgery with general anesthesia and muscle relaxants. The approval is expected within 12-15 months.

"*We are in the final stage regarding CE marking for TetraGraph and OnZurf probe. This means that we are expecting an extremely exciting time with a broad market launch of our products, where we are already experiencing a high demand",* says Lena Söderström, CEO of Senzime.

Senzime will attend The MedTech Conference in San Jose, California, September 25th–27th, where Senzime was selected as one of only 10 companies to present the TetraGraph in their "Innovation Pavilion." The company will also have a booth at the American Society of Anesthesiologists (ASA) Annual Meeting in Boston, MA in October - the largest anesthesia education meeting in the world. A new study of the TetraGraph monitor's usability will be presented at this meeting by investigators at the University of Debrecen, Hungary.

Every year, over 70 million patients undergo surgery and receive muscle relaxant drugs. Research has shown that over 30 percent of patients suffer from postoperative complications if objective neuromuscular monitoring is not used. The easy-to-use TetraGraph anesthesia monitoring system can monitor and objectively determine when the patient is sufficiently recovered to sustain spontaneous breathing.

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TO THE EDITORS

About Senzime

Senzime develops unique patient-oriented monitoring systems that make it possible to assess patients' biochemical and physiological processes before, during and after surgery. The portfolio of technologies includes bedside systems that enable automated and continuous monitoring of life-critical substances such as glucose and lactate in both blood and tissues, as well as systems to monitor patients' neuromuscular function perioperatively and in the intensive care medicine setting. The solutions are designed to ensure maximum patient benefit, reduce complications associated with surgery and anesthesia, and decrease health care costs. 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 (ticker SEZI). FNCA is Certified Adviser for Senzime. www.senzime.com