Senzime updates and optimizes strategy for FDA approval

Press release: Uppsala, February 15, 2019. Senzime AB (publ) today announces the intent to re-submit the existing 510(k) application to the US Food and Drug Administration (FDA). Based on an updated version of the TetraGraph, the existing 510(k) application will be re-submitted and Senzime thereby seeks to decrease the overall time to FDA approval.

The FDA application is part of Senzime's strategic launch plan for the TetraGraph system, with primary focus of launching in Europe, Japan, Korea and the United States – central markets for monitoring patients undergoing surgery with general anesthesia and muscle relaxants.

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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 Sweden AB, +46 (0)8-528 00 399, info@fnca.se, is Certified Adviser for Senzime. www.senzime.com