

## **Senzime receives approval from The Swedish Medical Products Agency to start pivotal clinical trial**

The Swedish Medical Products Agency (MPA) has granted approval to Senzime AB to conduct a clinical study at Uppsala University Hospital. The approval follows a previous approval received from The Regional Ethical Review Board in April 2010, both of which are prerequisites for the planned clinical trial.

"This is a very important step for Senzime which allows the Company to proceed with its pivotal clinical study. We are addressing an important medical need - Continuous Blood Glucose Monitoring (cBGM) - with a technology and a system that has the potential to meet the high demands required in patient monitoring in intensive care units. We look forward to starting the trial as soon as possible following this approval", says Staffan Boström, CEO of Senzime.

The study will be conducted in close collaboration with the Thoracic Surgery and Anesthesia Department at Uppsala University Hospital. Blood sugar levels in patients undergoing intensive care will be monitored with Senzime's proprietary continuous, blood glucose sensing system.

### **New monitoring technology**

The need for new technology to continuously monitor patients' glucose levels (blood sugar) in the hospital setting is great since most existing systems lack the performance needed for this application. The current need and performance gap, pinpointing the demand for new monitoring technologies for cBGM, has been the subject of recent research<sup>1</sup>.

<sup>1</sup> Analysis: Continuous Glucose Monitoring during Intensive Insulin Therapy. Journal of Diabetes Science and Technology 2009;3(4):960-963.

### **The Clinical Diagnostics Market**

Senzime provides a proprietary sensor based system for bedside patient monitoring. Current focus is to launch the instrument for monitoring of patients in operating rooms and intensive care units. Due to the adoption of tight glycaemic control schemes, or Intensive Insulin Therapy, in these settings it is becoming more and more crucial for hospitals to have, or put in place methods for the continuous monitoring of glucose in whole blood.

US based industry analysts Frost & Sullivan (2005) estimates that 6,000 ICU's in the U.S. manage roughly 55,000 patients per day. Continuous glucose checks on all patients would represent significant demand, much of which is unmet with existing technologies. The global situation mirrors the US.

Senzime's view is that it has developed a solution to this need.

**For more information, please visit [www.senzime.com](http://www.senzime.com) or contact:**

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### **About Senzime**

Uppsala based Senzime, founded in 1999, has developed a biosensor which makes it possible to continuously and automatically monitor critical components in complex biological fluids. The need for such on-line measurements is increasing in a range of industries, for example in pharmaceutical production and health care.

Senzime's product offering consists of a measurement instrument and disposable sensor units, similar to the machine/filter combination one would find in a modern dialysis machine.

In parallel with working in the pharmaceutical production field (bioreactors/fermentation), Senzime has adapted its instrumented system for automated and continuous monitoring of whole blood glucose in intensive care units. The first patients were monitored by a Senzime instrument in June 2009.

The company's largest owners are members of the Crafoord family, primarily known for its key role in developing Swedish medical device company Gambro.

Senzime is a publicly listed company and its shares trade at Swedish AktieTorget ([www.aktietorget.se](http://www.aktietorget.se)).