

## **LIFECARE ASA RECEIVES REGULATORY FEEDBACK ON FIRST-IN-HUMAN APPLICATION, AND HAS ENGAGED LINK MEDICAL AS ADVISOR FOR A RE-SUBMISSION**

**Bergen, Norway 9 March 2026 - Lifecare ASA, a MedTech company developing next-generation implantable Continuous Glucose Monitoring (CGM) technology, announces that the Norwegian Medical Products Agency (NOMA) has completed its review of the company's application to conduct a clinical investigation of its CGM implant.**

Following its assessment, NOMA concluded that the submitted documentation is not yet sufficient to support authorization of the clinical investigation, and that additional documentation and clarifications are required before approval can be granted. The company will address these items in the re-submission. While the application was formally rejected at this stage, Lifecare emphasizes that such outcomes are not uncommon in the regulatory process for first-in-human studies involving innovative medical technologies. Regulatory reviews frequently involve iterative feedback to ensure that all safety and documentation requirements are fully addressed before clinical trials begin.

The company considers the feedback constructive and valuable and views the review as an important step in the ongoing regulatory process. The review has helped further clarify regulatory expectations and provides clear guidance on the areas where additional technical documentation and validation should be strengthened.

Lifecare has engaged LINK Medical for assistance in the final phase toward regulatory approval for the first-in-human study.

"We appreciate the detailed review and the constructive input from NOMA," said Joacim Holter, CEO of Lifecare ASA. "Regulatory dialogue is an important part of developing breakthrough medical technologies. Importantly, the feedback primarily relates to technical documentation and supporting validation, including areas such as biocompatibility, sterilization procedures and manufacturing controls, rather than the underlying scientific rationale or intended use of the technology. The feedback we have received provides clear direction for the remaining documentation updates following the significant progress already achieved during the review process."

The Lifecare sensor is an implantable continuous glucose monitoring technology designed to measure glucose levels using osmotic pressure sensing. The upcoming clinical investigation is intended to evaluate the device's accuracy and performance in humans as part of the development pathway toward a future commercial product.

The company remains committed to advancing the technology and progressing toward clinical validation and future regulatory approval.

**About us**

Lifecare ASA is a medical sensor company developing technology for sensing and monitoring of various body analytes. Lifecare's focus is to bring the next generation of Continuous Glucose Monitoring systems to market. Lifecare enables osmotic pressure as sensing principle. Lifecare's sensor technology is suitable for identifying and monitoring the occurrence of a wide range of analytes and molecules in the human body and in pets.

**Contacts**

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