

LIFECARE RECEIVES ETHICS APPROVAL TO INITIATE FIRST-IN-HUMAN TRIAL IN NORWAY

Bergen, Norway, 5 August 2025 – Lifecare ASA (LIFE), a MedTech company developing next-generation Continuous Glucose Monitoring (CGM) technology for diabetes management, is pleased to announce that it has received approval from the Regional Committee for Medical and Health Research Ethics (REK) in Norway for its planned first-in-human trial of the implantable GCM sensor.

This marks a significant milestone, bringing Lifecare one step closer to initiating regulatory testing of its wireless glucose sensor for human use. The approved trial is designed to assess the safety, tolerability, and glucose-sensing accuracy of the implant in individuals with type 1 diabetes.

“We are grateful for REK’s endorsement of our study protocol. This approval reflects the scientific and ethical integrity of our work. It is a key step toward bringing a discreet, reliable and user-friendly CGM solution to people living with diabetes,” says Joacim Holter, CEO of Lifecare ASA.

The REK approval is conditional upon minor documentation updates and does not represent the final regulatory clearance to initiate the trial. Lifecare is currently awaiting final approval from the Norwegian Medicines Agency (Direktoratet for medisinske produkter), the national authority responsible for clinical trial authorization, before the trial can begin.

The first-in-human trial will be conducted in Norway and Germany, in collaboration with leading academic and clinical partners. Professor Simon Dankel, a recognized expert in metabolic research and head of the Research Unit for Health Surveys (RUHS) at the University of Bergen, will serve as Principal Investigator. The RUHS in Bergen will host the Norwegian clinical trial site.

This milestone follows previously announced technical verifications confirming achievements demonstrating that Lifecare’s GCM system meets core radio frequency (RF) and electromagnetic compatibility (EMC) requirements. These successful tests demonstrated the device’s ability to wirelessly transmit glucose data safely and reliably, a prerequisite for real-world use.

Together, the technical verifications and ethics approval highlight Lifecare’s consistent progress toward regulatory readiness and clinical evaluation of its implantable CGM technology.

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 (“**CGM**”) 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

For further information, please contact:

Joacim Holter, CEO, joacim.holter@lifecare.no, +47 40 05 90 40

Renete Kaarvik, CFO, renete.kaarvik@lifecare.no, +47 94 83 82 42