

LIFE – STUDY PROTOCOL HAS BEEN FINALIZED FOR SUBMISSION TO REGULATORY AUTHORITIES

Bergen, Norway, 10 October 2024: Today, Lifecare ASA (LIFE), a clinical stage medical sensor company developing the next generation Continuous Glucose Monitor (CGM), can announce that we have internally concluded on the next human study protocol to progress with our clinical sensor development towards regulatory approval.

Reference is made to the Q2 report 27 August 2024 when the company presented the progress plan for studies and regulatory compliance in 2024, including preparations and regulatory approval for CE study for clinical use (LFC-SEN-003).

A working group consisting of Lifecare's CSO Prof. Prof. Dr. Andreas Pfützner, member of Board Prof. Dr. Lutz Heinemann and Chairman of the Scientific Advisory Board Prof. David C. Klonoff has prepared and concluded on a draft protocol for a long-term human clinical study that will be presented to relevant regulatory authorities. As set forth in the progress plan for studies and regulatory compliance, it is planned to submit the protocol by end of 2024. However, the working group emphasizes that the submission of the study protocol is pending Sencell (for human) product design freeze.

In preparations for submitting the protocol to the regulatory authorities, we will engage a Contract Researcher Organization (CRO) to assist us in the processes and conclude on study sites for the clinical trials. One of these sites will be at Pfützner Science and Health GmbH in Mainz, Germany, which also conducted the first-in-human clinical Sencell study.

- This is a clear indication that we have come a step further in the preparations for the next study phase, the CE study for clinical use. The draft protocol will be submitted as soon as we are ready to engage a CRO and can conclude the design freeze of Sencell. Our aim is to meet these targets by end of year and submit for approval, says CEO Joacim Holter at Lifecare ASA.

About us

Lifecare ASA is a clinical stage medical sensor company developing technology for sensing and monitoring of various body analytes. Lifecare's main focus is to bring the next generation of Continuous Glucose Monitoring ("**CGM**") systems to market. Lifecare enables osmotic pressure as sensing principle, combined with the ability to manipulate Nano-granular Tunnelling Resistive sensors ("**NTR**") on the sensor body for read-out of pressure variations. Lifecare's sensor technology is referred to as "Sencell" and is suitable for identifying and monitoring the occurrence of a wide range of analytes and molecules in the human body and in pets.



PRESS RELEASE
10 October 2024 07:00:00 CEST

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