Press Release
21 May 2025 07:00:00 CEST

First Patient Enrolled in Clinical Pilot Study with Neola® on Preterm Born Babies

Neola Medical today announces that the first baby has been successfully included in the ongoing clinical pilot study on preterm born babies in Sweden with the company's continuous lung monitoring device, Neola®. This marks the very first time Neola® has been monitoring the lungs of a baby in its target patient group in neonatal intensive care, representing another step forward in the company's efforts to validate the technology's potential to enhance neonatal care by enabling earlier detection and intervention for pulmonary complications.

"This marks a truly meaningful milestone for Neola Medical. For the first time, our medical device, Neola® is being used for monitoring the lungs on its target patient group, preterm born babies, in neonatal intensive care," says CEO Hanna Sjöström

The clinical pilot study focuses on the safety and continuous monitoring with Neola® in a neonatal intensive care setting. In addition, it is designed to demonstrate both the utility of the product and its compatibility with the clinical environment. The study team at Södra Älvsborgs Sjukhus in Borås, consisting of experienced neonatologists and neonatal nurses, continues to enroll additional participants, with the goal of completing the clinical pilot study in the coming months.

Once all enrolled babies have completed the study and the data has been analyzed, results will be concluded in accordance with common practice and established standards for clinical evaluations.

About the Clinical Pilot study in Sweden
Neola Medical's first clinical pilot study is being conducted at the neonatal intensive care unit at Södra Älvsborgs Sjukhus in Borås, Sweden. The study is designed to evaluate the safety and performance of Neola® in monitoring the lungs of preterm born babies. A total of 10 babies in neonatal intensive care with a gestational age from 28 weeks and a weight between 1000–3000 grams are included. The study is expected to run for approximately four months. Findings from this first clinical study on preterm born babies can contribute additional input to optimizing and refining Neola®, aiming to ensure it meets the specific needs of this vulnerable and unique patient group. The results will furthermore guide preparations for the pivotal U.S. clinical study that will be instrumental in supporting the planned FDA application for market approval in the U.S.

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About Neola Medical
Neola Medical AB (publ) develops an innovative medical technology device for non-invasive, continuous lung monitoring and real-time alerts of potentially life-threatening lung complications in preterm born babies. By enabling instant detection, the technology aims to support earlier intervention, improve clinical decision-making, enhance long-term outcomes, and ultimately contribute to saving lives. The patented, cutting-edge technology was developed at Lund University in Sweden and is based on a spectroscopic method that measures changes in lung volume and oxygen gas concentration. Neola Medical builds on Sweden's longstanding legacy of medical technology innovation and contributions to global health care. Neola Medical was founded in 2016 and is listed on NASDAQ First North Growth Market (ticker: NEOLA). Read more at www.neolamedical.com. The company's Certified Adviser is FNCA Sweden AB.

Attachments
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