Press Release
25 March 2025 07:00:00 CET

Neola Medical Signs Agreement with Södra Älvsborgs Sjukhus in Borås to Initiate Clinical Pilot Study on Preterm Born Babies

Neola Medical is pleased to announce the signing of a contract with Södra Älvsborgs Sjukhus in Borås, to conduct the company's first clinical pilot study on preterm born babies, with its continuous lung monitoring device, Neola®. With the contract in place, Neola Medical can initiate the first clinical pilot study to evaluate Neola® within its target patient group.

"This signed agreement represents another important step forward for Neola Medical, as we prepare for the start of our first clinical pilot study on preterm born babies in Sweden. The hospital's neonatal expertise and commitment to advancing care for preterm born babies make them an ideal study site for this important phase of our development.", says CEO Hanna Sjöström

The contract ensures access to the neonatal intensive care unit at the hospital, where the study will be conducted by a team of experienced neonatologists and nurses. Extensive preparations have been finalized, including regulatory approvals from the Swedish Medical Products Agency (Läkemedelsverket) and the Swedish Ethical Review Authority (Etikprövningsmyndigheten). Comprehensive training for clinical staff on the use of Neola® has been conducted and preparations for the start of the study are in progress.

About Södra Älvsborgs Sjukhus
The Neonatal Department at Södra Älvsborgs Hospital (SÄS) in Borås provides specialized care for preterm infants and critically ill newborns who require more advanced medical attention than what can be offered in a standard maternity ward. The department has 11 neonatal intensive care unit (NICU) beds and consists of two intensive care units and a family unit. SÄS is also a teaching hospital for neonatology, actively engaged in the training and education of future specialists in the field.

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, with initiation planned in 2025. 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 revolutionizing medical technology device for non-invasive continuous lung monitoring and real-time alerts of life-threatening lung complications of preterm born infants. Immediate detection of complications provides the possibility of early treatment, improved health care and healthier lives for preterm born infants. The patented cutting-edge technology is developed at Lund University in Sweden and based on a spectroscopic method that measures lung volume changes and oxygen gas concentration. Neola Medical is building on a historic Swedish legacy of medical technology innovation and invaluable contributions to global health care. The company 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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