Press Release
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Neola Medical receives approval by Swedish Authorities to initiate Clinical Pilot Study on Preterm Born Babies in Sweden

Neola Medical today announces approval from the Swedish Medical Products Agency (Läkemedelsverket) and the Swedish Ethical Review Authority (Etikprövningsmyndigheten) to commence clinical pilot study on preterm born babies in Sweden, with its medical device for continuous lung monitoring, Neola®. The study will evaluate the safety and performance of Neola® in preterm born babies, marking the first clinical study with Neola® on its target patient group. Additionally, the study serves as a preparatory step for the pivotal clinical study on preterm born babies in the U.S.

The study will be conducted at a Swedish hospital with a total of 10 preterm born babies in neonatal intensive care. Patients with a gestational age from 28 weeks and a weight between 1000 and 3000 grams are included in the study. The study is expected to run for approximately four months, with initiation planned in 2025.

“This study marks a milestone as the first evaluation of Neola® in its target patient population, preterm born babies, underscoring our commitment to improving neonatal care. Securing approval for clinical studies in this vulnerable population is a rigorous process, highlighting the company’s ability to navigate stringent regulatory requirements.”, says CEO Hanna Sjöström.

Conducting clinical studies with Neola® on its target patient population is important, as preterm born babies differ significantly from full-term newborns. 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 our planned FDA application for market approval in the U.S.

To initiate the clinical pilot study on preterm born babies in Sweden, approval is required from both the Swedish Medical Products Agency (Läkemedelsverket) and the Swedish Ethical Review Authority (Etikprövningsmyndigheten). The received approval from both regulatory bodies now paves the way for the commencement of the clinical pilot study on preterm born babies in Sweden.

Clinical study history with the technology:

- 2021-2022: A large investigator-initiated and independent clinical study was conducted at the INFANT Centre at Cork University Hospital in Ireland. A total of 100 full-term newborns participated in the study, and the results demonstrated that the technology is safe and well tolerated for measuring the oxygen in the lungs. Oxygen detection in the lungs was successfully achieved in all participating infants.
- 2015-2018: An EU-funded project, including preclinical and clinical studies on healthy full-term newborns, laid the foundation for the company’s product, Neola®. An additional clinical study involving 12 full-term newborn babies was conducted in Lund. The study demonstrated clinical acceptance of the measurements and the design of the probes, which are attached to the baby’s chest.
- 2012-2013: Clinical research studies involving a total of 32 full-term newborns were conducted, and the results demonstrate the feasibility of measuring gas in the lungs of full-term newborns.

- 2010: The initial lung measurements were conducted on one full-term newborn baby at Lund University Hospital.

For more information about the studies and published articles, visit Neola Medical's website: https://www.neolamedical.com/our-studies/

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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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