Press communication
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Clinical study on 100 newborn babies with Neola Medical's medical technology device completed, positive subgroup results presented

The recruitment of 100 newborn babies to the clinical study NIOMI (Non-Invasive Lung Oxygen Monitoring in Term Infants) at University College Cork, Ireland, have now been completed. Positive subgroup results have been reported from the study, in which Neola Medical's medical technology device Neola® is used. The clinical study investigates the possibility to give real-time information about the lung function in newborn babies. Subgroup results from the first 50 newborn babies participating in the study was presented at a conference in the U.S. in April 2022. Now 100 newborn babies have participated in the clinical study after a successful recruitment. This is the largest clinical study ever with the Neola® technology. During the fall analyzes of the data is being performed for the purpose of publishing the results in scientific journals.

In the end of 2021, University Cork College initiated a clinical study at the Infant Centre, Ireland, to investigate the possibility to provide real time information on the lung function of newborn babies. The study includes 100 newborn babies and have already shown positive results regarding the measuring of the gaseous volume of the lungs by Neola®, the company's medicine technology device for continuous monitoring of lungs. The influence of the location of the probes on the signals were examined, which provide information on how to optimally place the probes on the chest of the infant for best monitoring performance.

"Thanks to the fact that the parents understand the benefits with Neola® for the development of the neonatal intensive care it has been easy to recruit babies to the clinical study. Now all 100 babies have been recruited and the positive results we have seen on the first fifty babies in the study confirms that the technology works well for measurements on newborns' lungs, which strengthens our perception of NEOLA®'s future position in neonatal intensive care. The comprehensive data resulting from this study could be important in the decision making for buyers of Neola®, and it is of particular importance as the study is user initiated and independent of the company. The study results are of great importance for the upcoming commercialization of Neola®.", says Hanna Sjöström, CEO at Neola Medical.

This is the largest clinical study so far that has been initiated with Neola®. Jurate Panaviene, clinical researcher at INFANT Research Centre at University College Cork, Ireland, explains: "Many parents are motivated by the fact that the study aims to develop the technology that can be used to help newborn babies. They are grateful that their babies were born healthy and they are happy to contribute to better care for families with unhealthy babies in the future."

About the NIOMI study
The study is planned to include up to 100 infants and begins with newborns without respiratory issues. In the next phase, the study will also include newborns with different types of breathing problems and infants in different weight classes. More precisely, the study will evaluate the placement of the Neola® probes in different areas of the infants' chest. The study is led by Professor Eugene Dempsey, Horgan Chair in Neonatology, INFANT Center, University College Cork (UCC).

About Neola®
Neola® is a medical device for continuous and non-invasive lung monitoring of premature babies developed by Neola Medical. The system measures changes in lung volume and oxygen concentration in the lungs of premature infants with the possibility of immediately detecting complications such as respiratory failure, a blocked airway, or a misplaced tracheal tube. This means that healthcare professionals are alerted to complications in real time and can treat patients directly.

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Neola Medical AB (publ) develops medical technology device for continuous monitoring of preterm born infants' lungs. Immediate detection of complications provides the possibility of early treatment and improved health care. The patented technology is based on a spectroscopic method developed at Lund University in Sweden. The company was founded in 2016 as a wholly owned subsidiary of Gasporox AB (publ) under the name GPX Medical AB. The company 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.