Press Release
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Neola Medical Receives FDA Breakthrough Device Designation

Neola Medical AB (publ) today announces that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation for Neola®, the Company's medical device for non-invasive, continuous lung monitoring in preterm born babies, with the intended use to support timely detection of potentially life-threatening lung collapse.

The designation represents a significant regulatory and strategic milestone for Neola Medical and its U.S. regulatory pathway. Through the Breakthrough Devices Program, Neola Medical gains the opportunity for more frequent and interactive communication with the FDA, as well as prioritized review of regulatory submissions.

"This is an important recognition of the potential of Neola® to address a critical unmet need in neonatal intensive care," says Hanna Sjöström, CEO of Neola Medical. "Receiving Breakthrough Device Designation from the FDA is a major milestone for Neola Medical and strengthens our U.S. regulatory pathway. It gives us the opportunity for a more direct and prioritized dialogue with the FDA, which may support a more efficient regulatory process and accelerate our route to market. Our objective is to bring Neola® one step closer to the preterm born babies who benefit from earlier detection of life-threatening lung collapse."

The FDA Breakthrough Device Designation supports Neola Medical's focus on high-value clinical use cases where continuous lung monitoring may provide meaningful clinical benefit, particularly in the detection of life-threatening lung collapse (pneumothorax), a severe pulmonary complication. The Company will now continue its regulatory and clinical preparations in the United States, including further dialogue with the FDA regarding the evidence required to support future market authorization.

About the FDA Breakthrough Devices Program
The FDA Breakthrough Devices Program is designed to provide patients and healthcare providers with more timely access to medical devices that have the potential to provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. Devices granted Breakthrough Device Designation benefit from more frequent and interactive communication with the FDA during development, as well as prioritized review of subsequent regulatory submissions. The designation does not constitute market approval, clearance, or authorization by the FDA.

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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 collapse 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 near-infrared light measurements in the lungs. 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.

This information is information that Neola Medical is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2026-09-04 19:38 CEST.

Attachments
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