# Vapotherm® Receives CE Mark for Oxygen Assist Module in the European Union

EXETER, N.H.--(BUSINESS WIRE)-- Vapotherm, Inc. (NYSE: VAPO) today announced that it has received the CE Mark for its Vapotherm Oxygen Assist Module (OAM). When used with a Precision Flow® system, the Vapotherm OAM helps clinicians keep their patients within the target oxygen saturation range more effectively than with manual control alone. Keeping babies in the prescribed oxygen saturation range may reduce the health risks associated with dosing too much, or too little oxygen – such as visual or developmental impairment in premature infants.

“Oxygen is a deadly, dangerous, life-giving drug with a narrow therapeutic index and it can be especially dangerous for babies,” said Joe Army, President and CEO of Vapotherm. “Too much or too little oxygen can lead to serious consequences. We are very proud to be able to offer clinicians a new tool in helping to maintain appropriate clinical oxygen levels in these babies.”

Clinicians focus significant effort on maintaining blood oxygen saturation within prescribed ranges in order to address these potential consequences, which are significant in scope. For example, more than 180,000 premature babies worldwide develop some degree of retinopathy of prematurity (ROP)—putting them at risk for visual impairment, including blindness, due to too much oxygen exposure. Additionally, the prevalence of ROP is increasing as infant mortality rate decreases.

The effectiveness of the Vapotherm OAM algorithm was validated in a 2018 study published by Reynolds and colleagues in the Archives of Disease in Childhood: Fetal and Neonatal Edition. The data show that trained staff using manual controls alone were able to maintain premature infants’ oxygen saturation in the physician-prescribed target range 49% of the time. When using the Vapotherm device, the staff were able to maintain the target oxygen saturation range 80% of the time, while at the same time requiring significantly fewer adjustments to the equipment. The study refers to the algorithm in the OAM by its prototype name of IntellO2.

Vapotherm OAM integrates with Vapotherm’s Precision Flow system. The Precision Flow system provides Hi-VNI® Technology, which has been clinically proven to be a mask-free and seal-free alternative to nCPAP as well as noninvasive positive pressure ventilation (NiPPV) in neonates and adults.

Vapotherm, Inc. (NYSE: VAPO) is a publicly traded developer and manufacturer of advanced respiratory technology based in Exeter, New Hampshire, USA. The company develops innovative, comfortable, non-invasive technologies for respiratory support of patients with chronic or acute breathing disorders. Over 2.0 million patients have been treated with Vapotherm Hi-VNI Technology. For more information, visit www.vapotherm.com.

Hi-VNI® Technology is mask-free noninvasive ventilation for spontaneously breathing patients and a front-line tool for relieving respiratory distress—including hypercapnia, hypoxemia, and dyspnea. It allows for the fast, safe treatment of undifferentiated respiratory distress with one user-friendly tool. Hi-VNI Technology’s mask-free interface delivers optimally conditioned breathing gases, making it comfortable for patients and reducing the risks and care complexities associated with mask therapies. While being treated, patients can talk, eat, drink and take oral medication.

**Website Information:** Vapotherm routinely posts important information for investors on the Investor Relations section of its website, http://investors.vapotherm.com/. Vapotherm intends to use this website as a means of disclosing material, non-public information and for complying with Vapotherm’s disclosure obligations under Regulation FD. Accordingly, investors should monitor the Investor Relations section of Vapotherm’s website, in addition to following Vapotherm’s press releases, Securities and Exchange Commission filings, public conference calls, presentations and webcasts. The information contained on, or that may be accessed through, Vapotherm’s website is not incorporated by reference into, and is not a part of, this document.

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