FDA Grants Vapotherm® Oxygen Assist Module (OAM™) Breakthrough Device Designation

EXETER, N.H.--(BUSINESS WIRE)-- Vapotherm, Inc. (NYSE: VAPO) (“Vapotherm” or the “Company”), a global medical technology company focused on the development and commercialization of its proprietary Hi-VNI® Technology products that are used to treat patients of all ages suffering from respiratory distress, today announced that the U.S. Food and Drug Administration (FDA) recently granted Breakthrough Device Designation for the Company’s Oxygen Assist Module (OAM).

FDA’s Breakthrough Device Program is intended to help patients and healthcare providers receive more timely access to breakthrough technologies that have the potential to provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The program creates an expedited pathway for prioritized FDA review of the OAM. Separately, Vapotherm submitted an Investigational Device Exemption (IDE) for pediatric use of OAM to FDA.

“We are delighted that the FDA granted OAM Breakthrough Device Designation status and look forward to working closely with them to provide clinicians with a solution to more effectively keep their patients within the physician-prescribed target oxygen saturation range with significantly fewer manual adjustments to the equipment,” said Joe Army, President and CEO of Vapotherm.

Vapotherm OAM is a module for use with most versions of Vapotherm’s Precision Flow® systems. The Precision Flow system incorporates Hi-VNI® Technology, a mask-free and seal-free clinically validated alternative to nasal continuous positive airway pressure (nCPAP) as well as noninvasive positive pressure ventilation (NiPPV) in pediatrics and adults. When used with the Precision Flow system, the Vapotherm OAM assists staff in maintaining a targeted SpO2 (amount of oxygen in the blood) range.

The effectiveness of the Vapotherm OAM algorithm was evaluated 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 OAM device, the staff were able to maintain the target oxygen saturation range 80% of the time, while at the same time requiring significantly fewer manual adjustments to the oxygen delivered by the equipment. The study refers to the algorithm in the OAM by its prototype name of IntellO2.

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 2.1 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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