Mallinckrodt Announces an Expanded Rollout of the INOmax® EVOLVE™ DS Delivery System in U.S. Hospitals

October 10, 2024

– The INOmax EVOLVE DS is our next-generation nitric oxide delivery system that combines mini-cylinder technology, automation, integration, and interaction into one device[1] –

– The INOmax EVOLVE DS is now available for contracting and distribution for use in U.S. hospitals –

DUBLIN, Oct. 10, 2024 /PRNewswire/ -- Mallinckrodt plc, a global specialty pharmaceutical company, today announced the rollout of the U.S. Food and Drug Administration (FDA) cleared INOmax® EVOLVE™ DS delivery system for the delivery of INOmax® (nitric oxide) gas, for inhalation. This nationwide rollout follows the successful introduction of the INOmax EVOLVE DS Pilot program.

The INOmax EVOLVE DS is our next-generation inhaled nitric oxide delivery system with a fully integrated design and includes a primary delivery system, a monitoring system, an electronic blender, automated backup delivery, mini-cylinders, and more.[1] The INOmax EVOLVE DS is intended to help meet the needs of neonatal intensive care unit (NICU) patients and healthcare professionals by offering improved automation, which enhances safety features, and a streamlined design that elevates the user experience.[1]

Please see Applications and Device Warnings below.

INOmax is an FDA-approved treatment that is indicated to improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term (>34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in conjunction with ventilatory support and other appropriate agents.[2]

INOmax is **contraindicated** in the treatment of neonates dependent on right-to-left shunting of blood.[2]

Please see additional Important Safety Information for INOmax below.

"We are excited to enter the nationwide rollout phase of our next-generation INOmax delivery system for NICU patients and the hospital staff responsible for their care," said **Lisa French, Executive Vice President & Chief Commercial Officer**. "This innovation milestone reflects our long-standing commitment to providing delivery system options with comprehensive safety features.[1] We will continue to work closely with our customers to support availability of the INOmax EVOLVE DS delivery system."

A few of the many INOmax EVOLVE DS features include[1]:

- 1.4-lb mini-cylinders
- Automated pre-use checkout
- Pre-high-calibrated NO/NO_2 gas sensor modules and automatic low calibration
- Automatic cylinder switching when empty
- Electronic blender with automatic activation when a minimum amount of oxygen flow has been detected
- Electronic medical record connectivity that transfers over 100 data parameters[3]
- Touchscreen display with an easy-to-use interface

The comprehensive INOmax EVOLVE DS Pilot program provided users the opportunity for an extensive review of our next-generation delivery system. We appreciate each hospital's feedback including one **Respiratory Therapist's (RT)** statement that, "After using the INOmax EVOLVE DS during the pilot introduction, and in current use, it is evident that Mallinckrodt took the input from bedside RTs into account. The smaller cylinders and streamlined design make it easier to move the device around the hospital and store supplies."[1]

INOmax has a well-established efficacy and safety profile with more than 20 years on the market and over 875,000 patients treated globally.[2,4] In 2023, the INOmax EVOLVE DS was awarded the Human Factors and Ergonomics Society Stanley Caplan User-Centered Product Design Award, presented to teams that have demonstrated outstanding innovation and design for products, software, and systems. Mallinckrodt accepted the award on February 15, 2024.

If a customer is interested in learning more about the INOmax EVOLVE DS, they can reach out to their local representative or visit INOmax.com for the latest updates.

APPLICATIONS

The INOmax EVOLVE DS delivery system delivers INOmax (nitric oxide) gas, for inhalation. The EVOLVE DS must only be used in accordance with the indications, usage, contraindications, and warnings and precautions described in the INOmax package insert and labeling and is indicated for use in term and near term (>34 weeks gestation) neonates with hypoxic respiratory failure (HRF) associated with clinical or echocardiographic evidence of pulmonary hypertension. The EVOLVE DS is indicated for a maximum of 14 days of use.

DEVICE WARNINGS

- Abrupt discontinuation of INOmax can lead to worsening oxygenation and increasing pulmonary artery pressure (rebound pulmonary hypertension syndrome). To avoid abrupt discontinuation, use the eINOblender as a backup immediately to reinstate INOmax therapy and refer to the INOmax package insert.
- Do not discontinue INOmax delivery if the high NO_2 alarm activates. Assess the delivery system for proper setup while maintaining INOmax delivery and verify INOmax and/or FiO_2 are appropriate.
- Do not use equipment that is not specified as part of the system or that is not designed for INOmax mixtures. Using equipment that is not specified can cause the system to malfunction.
- If an alarm occurs, safeguard the patient first before performing troubleshooting procedures.
- Use only INOmax, pharmaceutical grade NO.

Rx Only

For technical assistance or for information on the INOmax EVOLVE DS delivery system, call (877) 566-9466.

IMPORTANT SAFETY INFORMATION (Cont'd)

- Abrupt discontinuation of INOmax may lead to increasing pulmonary artery pressure and worsening oxygenation.
- Methemoglobinemia and NO_2 levels are dose dependent. Nitric oxide donor compounds may have an additive effect with INOmax on the risk of developing methemoglobinemia. Nitrogen dioxide may cause airway inflammation and damage to lung tissues.
- In patients with pre-existing left ventricular dysfunction, INOmax may increase pulmonary capillary wedge pressure leading to pulmonary edema.
- Monitor for PaO_2, inspired NO_2, and methemoglobin during INOmax administration.
- INOmax must be administered using a calibrated FDA-cleared Nitric Oxide delivery system.

Please see Full Prescribing Information.

ABOUT MALLINCKRODT

Mallinckrodt is a global business consisting of multiple wholly owned subsidiaries that develop, manufacture, market, and distribute specialty pharmaceutical products and therapies. The company's Specialty Brands reportable segment's areas of focus include autoimmune and rare diseases in specialty areas like neurology, rheumatology, hepatology, nephrology, pulmonology, ophthalmology, and oncology; immunotherapy and neonatal respiratory critical care therapies; analgesics; and gastrointestinal products. Its Specialty Generics reportable segment includes specialty generic drugs and active pharmaceutical ingredients. To learn more about Mallinckrodt, visit www.mallinckrodt.com.

CAUTIONARY STATEMENTS RELATED TO FORWARD-LOOKING STATEMENTS

This release contains forward-looking statements, including with regard to INOmax (nitric oxide) gas, the INOmax EVOLVE™ DS delivery system, the potential of these products to improve health and treatment outcomes, their potential impact on patients and the availability of the INOmax EVOLVE™ DS delivery system inU.S. hospitals in the future. The statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those in the forward-looking statements: the effects of Mallinckrodt's recent emergence from bankruptcy; satisfaction of, and compliance with, regulatory and other requirements, including the clinical guidelines and protocols, and hospital policies and practices; actions of regulatory bodies and other governmental authorities; changes in laws and regulations; changes in market demand; issues with product quality, manufacturing or supply, or patient safety issues or adverse side effects or adverse reactions associated with INOmax (nitric oxide) gas and the INOmax EVOLVE™ DS delivery system; and other risks identified and described in more detail in the "Risk Factors" section and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Mallinckrodt's most recent Annual Report on Form 10-K , Quarterly Reports on Form 10-Q, and other filings with the SEC, all of which are available on its website. The forward-looking statements made herein speak only as of the date hereof and Mallinckrodt does not assume any obligation to update or revise any forward-looking statement, whether as a result of new

information, future events and developments or otherwise, except as required by law.

CONTACT

Media Inquiries
Green Room Communications
908-577-4531
mediainquires@grcomms.com

Investor Relations
Derek Belz
Vice President, Investor Relations
314-654-3950
derek.belz@mnk.com

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[1] INOmax EVOLVE™ DS Operation Manual. Mallinckrodt Pharmaceuticals.
[2] INOmax. Package insert. INO Therapeutics LLC; 2023.
[3] EVOLVE DS. Serial Data Protocol for versions 01.04.09 and later. Technical Bulletin. TB-23001. Mallinckrodt Pharmaceuticals. 2023.
[4] Data on File – Ref-01753. Mallinckrodt Pharmaceuticals.

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