Mallinckrodt Announces FDA Clearance of the INOmax® EVOLVE™ DS Delivery System and Approval of the INOmax® (nitric oxide) Mini-Cylinder

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– Company's next generation nitric oxide delivery system combines mini-cylinder technology, automation, integration, and interaction into one device[1] –

– The INOmax EVOLVE DS also earned recognition from the Human Factors and Ergonomics Society (HFES) for this year's innovative design –

DUBLIN, Dec. 7, 2023 /PRNewswire/ -- Mallinckrodt plc, a global specialty pharmaceutical company, today announced that the INOmax® EVOLVE ™ DS delivery system has been cleared by the U.S. Food and Drug Administration (FDA) for the delivery of INOmax® (nitric oxide) gas, for inhalation.

The INOmax EVOLVE DS delivers INOmax into the inspiratory limb of the patient breathing circuit in a way that provides a constant concentration of nitric oxide (NO), as set by the user, to the patient throughout the inspired breath. It uses a specially designed injector module, which enables tracking of the gas delivery system waveforms and the delivery of a synchronized and proportional dose of NO. It may be used with the ventilators and respiratory care devices for which INOmax EVOLVE DS has been validated.[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.

As a result of the FDA clearance, the INOmax EVOLVE DS will now become a next-generation nitric oxide delivery system with a fully integrated design and will include a primary delivery system, a monitoring system, an electronic blender, automated backup delivery, mini-cylinders, and more.[1] The INOmax EVOLVE DS can help meet the needs of NICU patients and providers by offering improved automation, which enhances safety features, portability for intrahospital transport, and a streamlined design that elevates the user experience.[1]

Dr. Peter C. Richardson, MRCP (UK), Executive Vice President & Chief Scientific Officer, said, "This achievement reflects our commitment over the past two decades to serve the needs of NICU patients by providing a next-generation INOmax delivery system with comprehensive safety features.[1] The FDA clearance of the INOmax EVOLVE DS is a major milestone for our company, the dedicated team members who made this possible, and most importantly, for our critically ill patients and the NICU staff responsible for their care."

The INOmax EVOLVE DS was also recently awarded the Human Factors and Ergonomics Society (HFES) Stanley Caplan User-Centered Product Design (UCD) Award for 2023. This award is presented each year to teams that have demonstrated outstanding innovation and design for products, software, and systems across several categories.

"The INOmax EVOLVE DS delivery system epitomizes the balance of thorough research, user-centered design, innovative solutions, and transformative outcomes. We commend the team behind the device for their exemplary work and contribution to the field," said **Adam Shames, Chair, PDTG UCD Award**.

The INOmax EVOLVE DS is not currently available for purchase, distribution, or use, but is expected to be available in U.S. hospitals in the first half of 2024.

INOmax has a well-established efficacy and safety profile with more than 20 years on the market and over 875,000 patients treated globally.[2,3]

For more details, please visit INOmax.com for the latest updates.

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.

APPLICATIONS

The INOmax EVOLVE DS and DS_{IR} Plus delivery systems deliver INOmax (nitric oxide) gas, for inhalation. These delivery systems must only be used in accordance with the indications, usage, contraindications, and warnings and precautions described in the INOmax package insert and labeling and are indicated for use in term and near term (>34 weeks gestation) neonates with HRF associated with clinical or echocardiographic evidence of pulmonary hypertension. These delivery systems are 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 EVOLVE DS eINOblender or the DS_{IR} Plus INOblender 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 systems or that is not designed for INOmax mixtures. Using equipment that is not specified can cause the systems to malfunction.
- If an alarm occurs, safeguard the patient first before performing troubleshooting procedures.
- Use only INOmax, pharmaceutical grade NO.

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

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 segments 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; cultured skin substitutes 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 INOmax® EVOLVE ™ DS delivery system in the U.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 of Mallinckrodt's most recent Annual Report on Form 10-K 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.

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References

[1] Data on File – Ref-05943. Mallinckrodt Pharmaceuticals.
[2] INOmax. Package insert. INO Therapeutics LLC; 2023.

[3] Data on File – Ref-01753. Mallinckrodt Pharmaceuticals.

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