Mallinckrodt Initiates Retrospective Study of the Use of Inhaled Nitric Oxide in COVID-19 Patients

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- Chart review is expected to collect real-world data on patients with respiratory complications associated with COVID-19 who received INOmax® (nitric oxide) gas, for inhalation in a hospital setting -

DUBLIN, Nov. 10, 2020 /PRNewswire/ -- Mallinckrodt plc, a global biopharmaceutical company, today announced initiation of a retrospective chart review study, titled "Nitric Oxide Treatment In COVID-19 Evaluation (NOTICE)" to collect real-world data on the use of INOmax® (nitric oxide) gas, for inhalation therapy in patients with respiratory complications associated with the novel coronavirus SARS-CoV-2 (COVID-19).

INOmax is indicated for the treatment of term and near-term neonates with hypoxic respiratory failure associated with pulmonary hypertension. The safety and efficacy of INOmax to treat lung complications associated with COVID-19 has not been evaluated or established by the U.S. Food and Drug Administration.

"We hope this retrospective chart review will help to further extend our understanding of the use of inhaled nitric oxide," said **Steven Romano, M.D., Executive Vice President and Chief Scientific Officer at Mallinckrodt**.

Mallinckrodt will partner with Pharmerit - an OPEN Health company - to collect data from approximately 200 hospitalized adult patients with a confirmed diagnosis of COVID-19 who were treated with INOmax for pulmonary complications associated with COVID-19 for at least 24 hours between January 1, 2020 and July 31, 2020. Patient data will be reviewed for the period from hospital admission to 30 days post-discharge.

The primary objectives of the study are as follows:

- Describe the disease course in patients initiating INOmax for management of COVID-19 symptoms
- Assess the clinical outcomes of patients who have received INOmax early (high P/F ratio or low OI) vs late (low P/F ratio or high OI)
- Describe the demographic and clinical characteristics of patients hospitalized with COVID-19 and treated with INOmax
- Describe treatments and procedures, and during the initial hospitalization, and survival at 30 days post-discharge in patients who are treated with INOmax
- Assess selected complications and adverse events as documented in the medical chart of initial hospitalization
- Evaluate healthcare resource use during initial hospitalization

COVID-19 is a contagious respiratory illness caused by a novel coronavirus. Patients with COVID-19 have mild to severe respiratory illness that can include symptoms such as cough, fever and shortness of breath.[1] In severe cases, COVID-19 can cause acute respiratory distress syndrome (ARDS) – a disorder in which fluid leaks into the lungs, making breathing difficult or impossible – and can lead to multi-organ failure and sometimes death.[1,2] To date, more than 200,000 patients in the U.S. have died from COVID-19.[3]

INOmax has been on the market in the U.S. since 2000 and is indicated for the treatment of term and near-term neonates with hypoxic respiratory failure associated with pulmonary hypertension. Please see Important Safety Information below. The safety and efficacy of INOmax and iNO for pulmonary complications associated with COVID-19 have not been established.

INDICATION

INOmax® (nitric oxide) gas, for inhalation, 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.

IMPORTANT SAFETY INFORMATION

- INOmax is contraindicated in the treatment of neonates dependent on right-to-left shunting of blood.
- 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, nephrology, pulmonology and ophthalmology; 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.

Mallinckrodt uses its website as a channel of distribution of important company information, such as press releases, investor presentations and other financial information. It also uses its website to expedite public access to time-critical information regarding the company in advance of or in lieu of distributing a press release or a filing with the U.S. Securities and Exchange Commission (SEC) disclosing the same information. Therefore, investors should look to the Investor Relations page of the website for important and time-critical information. Visitors to the website can also register to receive automatic e-mail and other notifications alerting them when new information is made available on the Investor Relations page of the website.

CAUTIONARY STATEMENTS RELATED TO FORWARD-LOOKING STATEMENTS

This release includes forward-looking statements concerning inhaled nitric oxide ("iNO") and the Company's INOmax product, including statements with regard to the proposed chart study, the potential impact of iNO on patients and anticipated benefits associated with its use. 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: satisfaction of regulatory and other requirements; actions of regulatory bodies and other governmental authorities; changes in laws and regulations; issues with product quality, manufacturing or supply, or patient safety issues; 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] Centers for Disease Control and Prevention Fact Sheet. What you need to know about coronavirus disease 2019 (COVID-19). Available at: https://www.cdc.gov/coronavirus/2019-ncov/communication/factsheets.html. Accessed October 19, 2020.

[2] Matthay MA, Aldrich JM, Gotts, JE. Treatment for severe acute respiratory distress syndrome from COVID-19. *Lancet Respir Med*. 2020. Published Online March 20, 2020. https://doi.org/10.1016/S2213-2600(20)30127-2.

[3] Centers for Disease Control and Prevention. Provisional death counts for coronavirus 2019 disease 2019 (COVID-19). Available at: https://www.cdc.gov/nchs/nvss/vsrr/covid19/index.htm. Accessed October 19, 2020.

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