



Mallinckrodt Comments on U.S. Court of Appeals Ruling in Patent Infringement Lawsuit against Praxair, Inc.

August 27, 2019

-- Company affirms commitment to INOmax® Total Care and belief that it will continue to have strong market acceptance due to comprehensive drug, device, service, disposables offering --

-- Development also continues for next-generation Evolve™ device --

Aug. 27, 2019 -- [Mallinckrodt Pharmaceuticals](#), a global biopharmaceutical company, is disappointed by today's decision by the U.S. Court of Appeals for the Federal Circuit upholding a Federal District Court's decision rejecting Mallinckrodt's patent infringement lawsuit against Praxair, Inc.'s nitric oxide drug product delivery system.

INOmax nitric oxide gas drug product is distributed with INOmax delivery systems. INOmax Total Care® is a comprehensive platform inclusive of drug, device, service and disposables that includes regular maintenance, quality assessment and quality control; physician and clinician device training; 24/7/365 customer and technical support; and rapid response of product availability in an emergency.

Mallinckrodt is confident its well-established presence and INOmax Total Care, its comprehensive product and service offering, are highly valued by customers. The company believes that the prospects for a newcomer succeeding in this market are by no means a foregone conclusion. Mallinckrodt remains committed to INOmax, and to the patients and customers it serves.

The company will consider all its available legal options.

About INOmax®

In the U.S., INOmax is indicated to improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term (>34 weeks gestation) neonates with HRF 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 NO₂ 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 PaO₂, methemoglobin, and inspired NO₂ during INOmax administration.
- INOmax must be administered using a calibrated, FDA-cleared Nitric Oxide Delivery System.

[Please see U.S. 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 statement includes forward-looking statements with regard to Mallinckrodt's legal proceedings against Praxair; the impact of the litigation on Mallinckrodt's future financial condition and operating results and the potential impact to patients; future regulatory filings related to nitric oxide drug products and any other statements regarding events or developments that Mallinckrodt believes or anticipates will or may occur 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: future legal proceedings and related outcomes; 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.

CONTACT

Media

Daniel Yunger
Kekst CNC
212-521-4879
mallinckrodt@kekstcnc.com

Investor Relations

Daniel J. Speciale, CPA
Vice President, Investor Relations and IRO
314-654-3638
daniel.speciale@mnk.com

Mallinckrodt, the "M" brand mark and the Mallinckrodt Pharmaceuticals logo are trademarks of a Mallinckrodt company. Other brands are trademarks of a Mallinckrodt company or their respective owners.

© 2019 Mallinckrodt. US-1901346 8/19