MALLINCKRODT AND NPXe ANNOUNCE FDA FAST TRACK DESIGNATION FOR PHASE 3 TRIAL OF INHALED XENON GAS THERAPY

-- Drug to be studied for improved functional outcomes and survival rates for patients resuscitated after a cardiac arrest --

STAINES-UPON-THAMES, UNITED KINGDOM and ABINGDON, UNITED KINGDOM AND BUFFALO, N.Y., USA - August 23, 2018 - Mallinckrodt plc (NYSE: MNK), a leading global specialty pharmaceutical company, and NPXe Limited ("NeuroproteXeon" or "NPXe") today announced that the United States Food and Drug Administration (FDA) recently granted Fast Track designation to NPXe's Phase 3 trial of xenon gas for inhalation in Post Cardiac Arrest Patients. Fast Track designations are provided to drug candidates that "treat a serious condition and fill an unmet medical need." Xenon gas for inhalation is an investigational drug, the safety and effectiveness of which have not yet been established.

The key benefits to recipients of a Fast Track designation include more frequent contact with the FDA on the development program and the option of Rolling Review, which allows a company to submit completed sections of the New Drug Application (NDA) for individual review by the Agency. This compares with the normal process where the entire NDA must be completed before submission. The frequency of communication under the Rolling Review better assures that questions and issues are resolved quickly, potentially leading to earlier drug approval and patient access.

Bill Burns, NPXe's Chief Executive Officer, commented, "Receiving Fast Track designation expedites the review process and, if approved, inhaled xenon gas will help treat patients with an unmet medical need. It further demonstrates we are taking the appropriate steps to rapidly bring this important treatment to the market."

"We are pleased to see the FDA recognize the potential value xenon gas for inhalation can provide in addressing these underserved patients who have a critical need," **said Steven Romano, M.D., Executive Vice President and Chief Scientific Officer at Mallinckrodt.** "We look forward to the upcoming start of the Phase 3 trial and learning more about this potential therapeutic option in a population of resuscitated cardiac arrest patients."

The companies anticipate the trial will commence in the coming months, with the first patients enrolled in the U.S.

About Xenon Gas for Inhalation in Post-Cardiac Arrest Syndrome (''PCAS'')
Xenon is a noble gas that has been used as an inhaled therapy in several studies to date. In PCAS, more N-methyl-D-aspartate receptors ("NMDAR", a calcium channel found in neurones) are activated, causing extreme ion imbalances, neuronal damage and cell death. Studies have shown that xenon may help to inhibit the NMDAR through a unique inhibition at the glycine-binding site and can help moderate the flow of damaging ions through the calcium channel. By mitigating neuronal damage and cell death, xenon may be able to improve functional outcomes and reduce mortality rates in survivors. The FDA has not yet established the safety and effectiveness of xenon gas for inhalation for PCAS.

About NPXe Limited
NPXe Limited is developing xenon gas for inhalation for the treatment of Post-Cardiac Arrest Syndrome. The Company has a Special Protocol Agreement with the FDA and A Scientific Working Party Agreement with the European Medicines Agency (EMA). Both the FDA and EMA

have provided the sought PCAS indication with Orphan Drug status. Orphan status prolongs the period of market exclusivity post approval. Mallinckrodt has licensed the rights to market xenon gas for inhalation in North America, Australia and Japan upon approval in each country. The rights to market xenon gas for inhalation in the EU, United Kingdom, Norway, Switzerland and Iceland are licensed to a third party.

About Mallinckrodt
Mallinckrodt is a global business that develops, manufactures, markets and distributes specialty pharmaceutical products and therapies. 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. 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 xenon gas for inhalation including expectations with regard to clinical trials, future regulatory actions and potential impact on patients. 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; future commercialization efforts; 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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