Mallinckrodt Provides a Regulatory Update on Terlipressin

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DUBLIN, Feb. 22, 2022 /PRNewswire/ -- Mallinckrodt plc (OTCMKTS: MNKKQ), a global biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) regarding the Company's New Drug Application (NDA) seeking approval for the investigational agent terlipressin to treat adults with hepatorenal syndrome (HRS), an acute and life-threatening syndrome involving rapid reduction in kidney function for which there is currently no FDA-approved treatment.[1,2]

Terlipressin is an investigational agent being evaluated for the treatment of HRS in the U.S., and its safety and effectiveness have not yet been established by the FDA.

Within the last two weeks, it became necessary to identify a new packaging and labeling manufacturing facility which meant that an inspection of the new facility by the FDA could not be completed by the PDUFA date. A satisfactory inspection is required before the NDA can be approved. This is the only outstanding issue noted in the CRL, and it is important to note that there were no safety or efficacy issues cited.

"We are working with the new facility to have it ready for inspection by the FDA," said **Steven Romano, M.D., Executive Vice President and Chief Scientific Officer at Mallinckrodt**. "We remain committed to this critically ill patient population, who currently have no approved treatment option in the U.S for HRS,[2] and we believe that there is a path to approval in 2022."

HRS is a form of impaired kidney function that occurs in individuals with advanced liver disease.[1] HRS is classified into two distinct types – a rapidly progressive type that leads to acute renal failure and a more chronic type that progresses over weeks to months.[1] HRS is estimated to affect between 30,000 and 40,000 Americans annually.[3,4] If left untreated, the rapidly progressive renal failure associated with HRS has a median survival time of approximately two weeks and greater than 80 percent mortality within three months.[2,5,6]

Terlipressin is one of the most studied pharmacological agents in HRS with more than 70 published manuscripts and presented abstracts on clinical data to date.[7] It has been approved for more than 30 years, available on five continents and is considered the standard of care for its indications in the countries where it is approved. [8,9,10]

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 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 with regard to terlipressin, including related to interactions with regulators, steps being taken related to its manufacturing, and its 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; 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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