Mallinckrodt Announces Resubmission of Terlipressin to the FDA for the Treatment of Hepatorenal Syndrome

June 13, 2022

DUBLIN, June 13, 2022 /PRNewswire/ -- Mallinckrodt plc (OTCMKTS: MNKKQ), a global biopharmaceutical company, today announced the resubmission of the Company's New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for the investigational agent terlipressin to treat adults with hepatorenal syndrome (HRS) involving rapid reduction in kidney function,[1] an acute and life-threatening condition[2] for which there is currently no FDA-approved treatment.[3]

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.

The resubmission follows ongoing discussions with the FDA resulting from a Complete Response Letter (CRL) received on February 18, 2022. In the two weeks prior to the PDUFA date of February 18, 2022, it became necessary to identify a new third-party packaging and labeling facility. While Mallinckrodt identified a new facility, an FDA inspection of the facility could not be completed by the February PDUFA date, resulting in the receipt of the CRL. For the NDA to be approved, the new facility must be inspection ready at the time of filing. This was the only outstanding issue noted in the CRL, as there were no safety or efficacy issues cited.

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.[4] It has been approved outside the U.S. for more than 30 years, is available on five continents, and is considered the standard of care for its two indications in the countries where it is approved.[5,6,7]

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, 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.

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.

CONTACT

Media Inquiries
Heather Guzzi

Senior Vice President, Green Room Communications
973-524-4112
hguzzi@greenroompr.com

Investor Relations
Daniel J. Speciale
Global Corporate Controller & Chief Investor Relations Officer
314-654-3638
daniel.speciale@mnk.com

Derek Belz
Vice President, Investor Relations
314-654-3950
derek.belz@mnk.com

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2 National Organization for Rare Disorders. Hepatorenal Syndrome. Available at: https://rarediseases.org/rare-diseases/hepatorenal-syndrome/. Accessed June 6, 2022.

3 Belcher, et al. Terlipressin and the Treatment of Hepatorenal Syndrome: How the CONFIRM Trial Moves the Story Forward. Am J Kidney Dis. 2022;79(5):737-745. doi:10.1053/j.ajkd.2021.08.016

4 Data on File – Ref-05488. Mallinckrodt Pharmaceuticals

5 Data on File – Ref-05482. Mallinckrodt Pharmaceuticals

6 FDA Cardiovascular and Renal Drugs Advisory Committee. Mallinckrodt Pharmaceuticals Terlipressin Advisory Committee Briefing Document NDA #022231. July 2020.

7 European Association for the Study of the Liver (EASL). Clinical practice guidelines for the management of patients with decompensated cirrhosis. *J Hepatol*. 2018;69(2):406-460.

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