Mallinckrodt Recognized as Industry Innovator at National Organization for Rare Disorders (NORD) 2023 Rare Impact Awards

May 5, 2023

– TERLIVAZ® (terlipressin) is the only FDA approved treatment for adults with HRS with rapid reduction in kidney function[1] –

DUBLIN, May 5, 2023 /PRNewswire/ -- Mallinckrodt plc (NYSE American: MNK), a global specialty pharmaceutical company, is pleased to announce it has received an award from the National Organization for Rare Disorders (NORD), recognizing it as an "Industry Innovator" for the creation of a treatment "to improve the lives of rare disease patients." Mallinckrodt is being recognized for the U.S. Food and Drug Administration (FDA) approval of TERLIVAZ® (terlipressin) for injection for the treatment of adults with HRS with rapid reduction in kidney function.[1]

TERLIVAZ, the first and only FDA-approved product indicated for the treatment of adults with Hepatorenal Syndrome (HRS) involving rapid reduction in kidney function,[1] an acute and life-threatening condition requiring hospitalization,[2] was approved for use on September 14, 2022.

Please see Limitation of Use and Important Safety Information, including Boxed Warning, below.

Peter Richardson, MRCP (UK), Executive Vice President & Chief Scientific Officer at Mallinckrodt, said, "We are honored to receive this award from NORD. TERLIVAZ® is an important treatment option for patients faced with this life-threatening condition and for their U.S. physicians who historically have had limited treatment options.[3] We are grateful to the patients who participated in our clinical trials, their caregivers and healthcare providers, and the team at Mallinckrodt who worked tirelessly to advance TERLIVAZ."

The presentation of awards took place the evening of May 4th, during NORD's 2023 Rare Impact Awards in Washington, D.C. Find more information on the Rare Impact Awards website, and see the full list of Industry Innovators in the recent press release.

About the National Organization for Rare Disorders (NORD)
With a 40-year history of advancing care, treatments and policy, the National Organization for Rare Disorders (NORD) is the leading and longest-standing patient advocacy group for the more than 25 million Americans living with a rare disease. NORD, a 501(c)(3) nonprofit, is dedicated to individuals with rare diseases and the organizations that serve them. NORD, along with its more than 330 patient organization members, is committed to improving the health and well-being of people with rare diseases by driving advances in care, research and policy. For more information, please visit https://rarediseases.org/.

About Hepatorenal Syndrome (HRS)
Hepatorenal syndrome (HRS) involving rapid reduction in kidney function[1] is an acute and life-threatening condition that occurs in people with advanced liver disease.[2] HRS is classified into two distinct types – a rapidly progressive type that leads to acute renal failure where patients are typically hospitalized for their care and a more chronic type that progresses over weeks to months.[2] HRS involving rapid reduction in kidney function[1] is estimated to affect between 30,000 and 40,000 Americans annually.[4, 5] If left untreated, HRS with rapid reduction in kidney function[1] has a median survival time of approximately two weeks and greater than 80 percent mortality within three months.[6]

INDICATION AND LIMITATION OF USE

TERLIVAZ is indicated to improve kidney function in adults with hepatorenal syndrome with rapid reduction in kidney function.

- Patients with a serum creatinine >5 mg/dL are unlikely to experience benefit.

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS OR FATAL RESPIRATORY FAILURE

- **TERLIVAZ may cause serious or fatal respiratory failure. Patients with volume overload or with acute-on-chronic liver failure (ACLF) Grade 3 are at increased risk. Assess oxygenation saturation (e.g., SpO_2) before initiating TERLIVAZ.**
- **Do not initiate TERLIVAZ in patients experiencing hypoxia (e.g., SpO_2 <90%) until oxygenation levels improve.**

Monitor patients for hypoxia using continuous pulse oximetry during treatment and discontinue TERLIVAZ if SpO_2 decreases below 90%.

Contraindications

TERLIVAZ is contraindicated:

- In patients experiencing hypoxia or worsening respiratory symptoms.
- In patients with ongoing coronary, peripheral, or mesenteric ischemia.

Warnings and Precautions

- **Serious or Fatal Respiratory Failure:** Obtain baseline oxygen saturation and do not initiate TERLIVAZ in hypoxic patients. Monitor patients for changes in respiratory status using continuous pulse oximetry and regular clinical assessments. Discontinue TERLIVAZ in patients experiencing hypoxia or increased respiratory symptoms.

  Manage intravascular volume overload by reducing or discontinuing the administration of albumin and/or other fluids and through judicious use of diuretics. Temporarily interrupt, reduce, or discontinue TERLIVAZ treatment until patient volume status improves. Avoid use in patients with ACLF Grade 3 because they are at significant risk for respiratory failure.

- **Ineligibility for Liver Transplant:** TERLIVAZ-related adverse reactions (respiratory failure, ischemia) may make a patient ineligible for liver transplantation, if listed. For patients with high prioritization for liver transplantation (e.g., MELD ≥35), the benefits of TERLIVAZ may not outweigh its risks.

- **Ischemic Events:** TERLIVAZ may cause cardiac, cerebrovascular, peripheral, or mesenteric ischemia. Avoid use of TERLIVAZ in patients with a history of severe cardiovascular conditions or cerebrovascular or ischemic disease. Discontinue TERLIVAZ in patients who experience signs or symptoms suggestive of ischemic adverse reactions.

- **Embryo-Fetal Toxicity:** TERLIVAZ may cause fetal harm when administered to a pregnant woman. If TERLIVAZ is used during pregnancy, the patient should be informed of the potential risk to the fetus.

Adverse Reactions

- The most common adverse reactions (≥10%) include abdominal pain, nausea, respiratory failure, diarrhea, and dyspnea.

Please click here to see full Prescribing Information, including Boxed Warning.

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, 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 contains forward-looking statements, including with regard to TERLIVAZ 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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References

[1] TERLIVAZ® (terlipressin) for injection. [Prescribing Information]. Mallinckrodt Hospital Products Inc.

[2] National Organization for Rare Disorders. Hepatorenal Syndrome. Available at: https://rarediseases.org/rare-diseases/hepatorenal-syndrome/. Accessed April 27, 2023.

[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] C Pant, B S Jani, M Desai, A Deshpande, Prashant Pandya, Ryan Taylor, R Gilroy, M OIyaee. Heptorenal syndrome in hospitalized patients with chronic liver disease: results from the Nationwide Inpatient Sample 2002-2012. *J of Investig Med.* 2016; 64:33-38.

[5] United States Census Bureau: Quick Facts. Available at: https://www.census.gov/quickfacts/fact/table/US/PST045218. Accessed April 27, 2023.

[6] Flamm SL, Brown K, Wadei HM., et al. The Current Management of Hepatorenal Syndrome–Acute Kidney Injury in the United States and the Potential of Terlipressin. *Liver Transpl*. 2021;27:1191-1202. https://doi.org/10.1002/lt.26072.

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