Mallinckrodt to Present Data on TERLIVAZ® (terlipressin) for Injection at the 2025 Digestive Disease Week (DDW) Annual Meeting

April 23, 2025

– Five presentations highlight TERLIVAZ research in adults with HRS with rapid reduction in kidney function,[1] also known as HRS-AKI[2] –

DUBLIN, April 23, 2025 /PRNewswire/ -- Mallinckrodt plc, a global specialty pharmaceutical company, today announced the presentation of four posters and one oral presentation on TERLIVAZ® (terlipressin) for injection in patients with hepatorenal syndrome (HRS) with rapid reduction in kidney function,[1] also known as HRS-acute kidney injury (AKI),[2] at Digestive Disease Week (DDW), taking place in San Diego, CA from May 3-6, 2025.

TERLIVAZ is the first and only FDA-approved product indicated to improve kidney function in adults with HRS with rapid reduction in kidney function,[1] also known as HRS-AKI,[2] an acute and life-threatening condition requiring hospitalization.[3] HRS-AKI is estimated to affect more than 42,000 Americans annually, approximately 0.01% of the U.S. population,[4] making it a very rare condition; and rates of HRS hospitalizations are increasing.[5]

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

"We'll be sharing the results of five clinical data analyses at DDW, as we continue to evaluate TERLIVAZ's impact in real-world situations," said **Peter Richardson, MRCP (UK), Executive Vice President & Chief Scientific Officer**. "We look forward to connecting with digestive disease colleagues in San Diego and discussing treatment options like TERLIVAZ for appropriate patients."

Abstract #4243460: Treatment and Outcomes of Terlipressin in Hospitalized Adults with Hepatorenal Syndrome-Acute Kidney Injury (HRS-AKI): Real-world Evidence in Patients by Transplant Waitlist Status[6]

- **Embargoed Until:** Monday, May 5, 2025; 12:01 a.m. PDT
- **Presenter:** Kavish R. Patidar
- **Session Type:** Oral Presentation
- **Session Title:** SOA - Cirrhosis in the Obese Patient
- **Session Date and Time:** Monday, May 5, 2025; 4:45 – 5:00 p.m. PDT

Abstract #4253811: A Comparative Analysis of Real-World HRS-AKI Treatment and Outcomes in the UK and US: Raw Clinical Data and Propensity Score-Matched Evidence[7]

- **Embargoed Until:** Tuesday, May 6, 2025; 12:01 a.m. PDT
- **Presenter:** Stevan A. Gonzalez
- **Session Type:** Poster Session
- **Session Title:** Portal Hypertension and Non Bleeding Complications of Cirrhosis: Encephalopathy, Ascites, and HRS
- **Session Date and Time:** Tuesday, May 6, 2025; 12:30 – 1:30 p.m. PDT

Abstract #4253534: Real-World Treatment and Outcomes in Hospitalized Patients with Hepatorenal Syndrome-Acute Kidney Injury and Alcohol-Associated Liver Disease[8]

- **Embargoed Until:** Tuesday, May 6, 2025; 12:01 a.m. PDT
- **Presenter:** Robert Wong
- **Session Type:** Poster Session
- **Session Title:** Portal Hypertension and Non Bleeding Complications of Cirrhosis: Encephalopathy, Ascites, and HRS
- **Session Date and Time:** Tuesday, May 6, 2025; 12:30 – 1:30 p.m. PDT

Abstract #4230360: Transforming Hepatorenal Syndrome-Acute Kidney Injury Treatment: A Win Ratio Analysis of

Terlipressin Versus Placebo[9]

- **Embargoed Until:** Tuesday, May 6, 2025; 12:01 a.m. PDT
- **Presenter:** Kavish R. Patidar
- **Session Type:** Poster Session
- **Session Title:** Portal Hypertension and Non Bleeding Complications of Cirrhosis: Encephalopathy, Ascites, and HRS
- **Session Date and Time:** Tuesday, May 6, 2025; 12:30 – 1:30 p.m. PDT

Abstract #4253824: Improving the Benefit-to-risk Profile: Efficacy Outcomes in Patients with Hepatorenal Syndrome-Acute Kidney Injury When Selected According to the Terlipressin Prescribing Information[10]

- **Embargoed Until:** Tuesday, May 6, 2025; 12:01 a.m. PDT
- **Presenter:** Michael P. Curry
- **Session Type:** Poster Session
- **Session Title:** Portal Hypertension and Non Bleeding Complications of Cirrhosis: Encephalopathy, Ascites, and HRS
- **Session Date and Time:** Tuesday, May 6, 2025; 12:30 – 1:30 p.m. PDT

These analyses were sponsored by Mallinckrodt Pharmaceuticals.

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 DIGESTIVE DISEASE WEEK® (DDW)

Digestive Disease Week® (DDW) is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association (AGA), the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW is an in-person and online meeting from May 3-6, 2025. The meeting showcases more than 5,600 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. More information can be found at www.ddw.org.

ABOUT HEPATORENAL SYNDROME (HRS)

Hepatorenal syndrome (HRS) is a life-threatening condition that occurs in people with advanced liver disease.[3] 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 (HRS-acute kidney injury (AKI)) and a more chronic type that progresses over weeks to months (HRS-chronic kidney disease (CKD)).[3] HRS-AKI is estimated to affect more than 42,000 Americans annually, approximately 0.01% of the U.S. population,[4] making it a very rare condition; and rates of HRS hospitalizations are increasing.[5] If left untreated, HRS-AKI has a median survival time of less than two weeks and greater than 80% mortality within three months.[2]

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; neonatal respiratory critical care therapies; 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.

CAUTIONARY STATEMENTS RELATED TO FORWARD-LOOKING STATEMENTS

This release contains forward-looking statements, including with regard to TERLIVAZ®, its potential to improve health and treatment outcomes, 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: the effects of Mallinckrodt's recent emergence from bankruptcy; satisfaction of, and compliance with, 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 or adverse side effects or adverse reactions associated with TERLIVAZ; and other risks identified and described in more detail in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Mallinckrodt's most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, 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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[1] TERLIVAZ® (terlipressin) for injection. [Prescribing Information]. Mallinckrodt Hospital Products Inc. 2023.

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[5] Singh J., Dahiya D.S., Kichloo A., et al. Hepatorenal Syndrome: A Nationwide Trend Analysis from 2008 to 2018. *Annals of Med*. 2021;53:1. 2018-2024 doi.org/10/1080/07853890.

[6] Patidar K.R., Barritt A.S. IV, Wong R., et al. Treatment and Outcomes of Terlipressin in Hospitalized Adults with Hepatorenal Syndrome-Acute Kidney Injury (HRS-AKI): Real-world Evidence in Patients by Transplant Waitlist Status. *Abstract to be presented in an oral presentation at the Digestive Disease Week Meeting.* May 2025.

[7] Gonzalez S.A., Allegretti A.S., Chirikov V.V., et al. A Comparative Analysis of Real-World HRS-AKI Treatment and Outcomes in the UK and US: Raw Clinical Data and Propensity Score-Matched Evidence. *Abstract to be presented in a poster presentation at the Digestive Disease Week Meeting.* May 2025.

[8] Wong R., Patidar K.R., Barritt A.S. IV, et al. Real-World Treatment and Outcomes in Hospitalized Patients with Hepatorenal Syndrome-Acute Kidney Injury and Alcohol-Associated Liver Disease. *Abstract to be presented in a poster presentation at the Digestive Disease Week Meeting.* May 2025.

[9] Patidar K.R., Hernaez R., Cullaro G., et al. Transforming Hepatorenal Syndrome-Acute Kidney Injury Treatment: A Win Ratio Analysis of Terlipressin Versus Placebo. *Abstract to be presented in a poster presentation at the Digestive Disease Week Meeting.* May 2025.

[10] Curry M.P., Pappas S.C., Marden M., et al. Improving the Benefit-to-risk Profile: Efficacy Outcomes in Patients with Hepatorenal Syndrome-Acute Kidney Injury When Selected According to the Terlipressin Prescribing Information. *Abstract to be presented in a poster presentation at the Digestive Disease Week Meeting.* May 2025.

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