Mallinckrodt to Present Data on Terlipressin in Patients with Hepatorenal Syndrome-Acute Kidney Injury (HRS-AKI) at Kidney Week 2025

October 30, 2025

– Two poster presentations will highlight research on the effects of paracentesis and CKD in adults with HRS-AKI[1,2] –

DUBLIN, Oct. 30, 2025 /PRNewswire/ -- Mallinckrodt plc, a global specialty pharmaceutical company, today announced the presentation of two posters on terlipressin in patients with hepatorenal syndrome-acute kidney injury (HRS-AKI), at Kidney Week 2025, the annual meeting of the American Society of Nephrology (ASN), taking place in Houston, TX, from November 5-9, 2025.

One poster being presented reviewed the impact of paracentesis on HRS-AKI patients treated with terlipressin or placebo.[1] The other poster being presented reviewed real-world outcomes of chronic kidney disease (CKD) in patients treated with terlipressin.[2]

TERLIVAZ® (terlipressin) for injection is the first and only FDA-approved product indicated to improve kidney function in adults with HRS with rapid reduction in kidney function,[3] also known as HRS-AKI,[4] an acute and life-threatening condition requiring hospitalization.[5] HRS is estimated to affect more than 60,000 Americans annually, approximately 0.01% of the U.S. population,[6] making it a rare condition; and rates of HRS hospitalizations are increasing.[7]

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

"The poster presentations at this year's ASN Annual Meeting aim to help expand our knowledge of the potential factors impacting appropriate HRS-AKI patients treated with TERLIVAZ, like pre-existing CKD or undergoing paracentesis," said **Christopher White, M.D., M.S.P.H., Senior Director, Hepatology Lead, Clinical Development and Medical Affairs, Mallinckrodt**. "The more clinical data and real-world experience available, the better, which helps to support our understanding of appropriate patients who are most likely to benefit from TERLIVAZ treatment."

These analyses were sponsored by Mallinckrodt Pharmaceuticals. Presentation details can be found below:

Poster #FR-PO0122: Association of Paracentesis with Hepatorenal Syndrome (HRS) Reversal: Insights from the CONFIRM Trial of Terlipressin (Terli) [1]

- **Presenter:** Juan Carlos Q. Velez, MD
- **Session Title:** AKI: Epidemiology and Clinical Trials
- **Session Date and Time:** Friday, November 7, 2025; 10:00 a.m. – 12:00 p.m. CT

This post hoc analysis of the Phase III CONFIRM clinical trial assessed the impact of paracentesis, a procedure to help relieve intra-abdominal pressure which may improve renal hemodynamics, in HRS-AKI patients treated with terlipressin.[1] Paracentesis was recorded from treatment initiation up to 14 days or until ≥1 serum creatinine (SCr) value ≤1.5 mg/dL while on treatment ≤24 hours after the last dose of study drug was recorded.[1]

Poster #SA-PO1188: Impact of CKD on Real-World Outcomes in Patients Treated with Terlipressin for HRS-AKI [2]

- **Presenter:** Xingyue Huang, PhD
- **Session Title:** CKD: Biomarkers and Emerging Tools for Diagnosis and Monitoring
- **Session Date and Time:** Saturday, November 8, 2025; 10:00 a.m. – 12:00 p.m. CT

This study reviewed a real-world cohort identified from the Premier U.S. hospital database using ICD-10, drug, and billing codes, to assess how pre-existing CKD impacts real-world treatment outcomes in adult patients hospitalized with HRS-AKI and treated with terlipressin.[2] Patient characteristics and key clinical outcomes were compared between those with and without CKD.[2]

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 HEPATORENAL SYNDROME (HRS)

Hepatorenal syndrome (HRS) is a life-threatening condition that occurs in people with advanced liver disease.[5] HRS is classified into two distinct types – a rapidly progressive type that leads to renal failure where patients are typically hospitalized for their care (HRS-acute kidney injury (AKI)) and a more chronic type that progresses slowly over weeks to months (HRS-chronic kidney disease (CKD)).[4,5] HRS is estimated to affect more than 60,000 Americans annually, approximately 0.01% of the U.S. population,[6] making it a 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 at three months.[4]

ABOUT MALLINCKRODT

Mallinckrodt is dedicated to enhancing lives by providing therapeutics that strive to address unmet patient needs, and is a world-class manufacturer of high-quality generics, sterile injectables, and active pharmaceutical ingredients.

Our company consists of multiple wholly owned subsidiaries that operate in two businesses. Our Brands business is focused on autoimmune and rare diseases in areas including endocrinology, gastroenterology, hepatology, neonatal respiratory critical care,

nephrology, neurology, pulmonology, ophthalmology, orthopedics, rheumatology, and urology. Our Par Health business includes generic drugs, sterile injectables, and active pharmaceutical ingredients. To learn more, visit www.MNK-Endo.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; changes in market demand; 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, subsequent Quarterly Reports on Form 10-Q, and other filings with the Securities and Exchange Commission (SEC), all of which are available on the SEC's website (www.SEC.gov) and Mallinckrodt's website (www.MNK-Endo.com). 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] Patidar K.R., Allegretti A., Cullaro G., et al. Association of Paracentesis with Hepatorenal Syndrome (HRS) Reversal: Insights from the CONFIRM Trial of Terlipressin (Terli). *Abstract to be presented in a poster presentation at the American Society of Nephrology (ASN) 2025 Annual Meeting.* November 2025.

[2] Huang X., Patidar K.R., Wong R., et al. Impact of CKD on Real-World Outcomes in Patients Treated with Terlipressin for HRS-AKI. *Abstract to be presented in a poster presentation at the American Society of Nephrology (ASN) 2025 Annual Meeting.* November 2025.

[3] TERLIVAZ® (terlipressin) for injection. [Prescribing Information]. Mallinckrodt Hospital Products Inc. 2023.

[4] Flamm S.L., Brown K., Wadei H.M., 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

[5] National Organization for Rare Disorders. Hepatorenal Syndrome. Available at: https://rarediseases.org/rare-diseases/hepatorenal-syndrome/. Accessed October 2025.

[6] United States Census Bureau: Quick Facts. Available at: https://www.census.gov/quickfacts/fact/table/US/PST045218. Accessed October 2025.

[7] Wong R.J., Balasubramanain J., Panaccio M., et al. Acute Kidney Injury and Hepatorenal Syndrome Among Hospitalized Patients With Chronic Liver Disease. *JAMA Netw Open.* 2025;8(5):e2511816. doi:10.1001/jamanetworkopen.2025.11816.

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