Mallinckrodt to Present Breadth of Data on TERLIVAZ® (terlipressin) for Injection in Adult Patients with Hepatorenal Syndrome (HRS) at the American Association for the Study of Liver Diseases (AASLD) 2023 Liver Meeting

November 8, 2023

– A total of 11 scientific abstracts from Mallinckrodt's research for adults with HRS with rapid reduction in kidney function[1] provide further insight into the clinical efficacy, safety, and real-world utility of TERLIVAZ treatment for appropriate patients –

– Mallinckrodt's presence to include three oral presentations and one AASLD Poster of Distinction –

DUBLIN, Nov. 8, 2023 /PRNewswire/ -- Mallinckrodt plc (OTCMKTS: MNKTQ), a global specialty pharmaceutical company, today announced the presentation of 11 scientific abstracts with findings from the latest clinical and health economics research with TERLIVAZ® (terlipressin) for injection for adult patients with hepatorenal syndrome (HRS) with rapid reduction in kidney function[1] during the American Association for the Study of Liver Diseases (AASLD) 2023 Liver Meeting, taking place November 10-14, 2023 in Boston, MA.

Experience the interactive Multichannel News Release here: https://www.multivu.com/players/English/9111651-mallinckrodt-aasld-2023-liver-meeting/

Included among Mallinckrodt's breadth of data for adults with HRS with rapid reduction in kidney function[1] are three oral presentations and one Poster of Distinction detailing research of clinical outcomes with TERLIVAZ[2,3,4] and real-world health economics outcomes for TERLIVAZ-treated patients with comorbidities.[5]

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] an acute and life-threatening condition requiring hospitalization.[6] HRS involving rapid reduction in kidney function[1] is estimated to affect more than 35,000 Americans annually and rates of HRS hospitalizations are increasing.[7,8]

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

"It is essential to continue research into the relationship between TERLIVAZ treatment and key factors impacting clinical outcomes, such as concomitant treatments, comorbidities, and real-world care environments, to provide further insights into the continued use of TERLIVAZ for patients with this critical condition," said **Khurram Jamil, MD, Vice President, Hepatology, Clinical Development & Critical Care.** "We are thrilled to be able to share findings from our 11 scientific presentations at this year's AASLD Liver Meeting with the medical community – a testament to the breadth and depth of Mallinckrodt's commitment to expanding our collective knowledge of HRS to help physicians diagnose and treat HRS patients as early and effectively as possible."

Highlights of Mallinckrodt's 11 scientific presentations at the AASLD 2023 Liver Meeting include:

- Three Oral Presentations:
  - Findings from a pooled analysis of the three largest-ever prospective studies to assess the safety and efficacy of TERLIVAZ in patients with HRS type 1 (HRS-1) in the U.S. and Canada (CONFIRM, REVERSE, and OT-0401) evaluating the impact of mean arterial pressure on HRS reversal from baseline to end of treatment with TERLIVAZ (Abstract #224).[2]
  - Health economics outcomes from a decision-analytic model projecting the benefit of TERLIVAZ treatment among patients with alcohol-related cirrhosis and HRS (Abstract #80).[5]
  - An analysis of the clinical outcomes associated with concomitant albumin dosing with TERLIVAZ for the treatment of HRS-acute kidney injury (HRS-AKI) (Abstract #211).[3]
- One AASLD Poster of Distinction:
  - Results from a post hoc analysis of the CONFIRM, REVERSE, and OT-0401 trials assessing the relationship between mean arterial pressure and TERLIVAZ in HRS-AKI reversal (Abstract #3052-A).[4]

Please see a complete list of Mallinckrodt-sponsored abstracts to be presented at the 2023 AASLD Liver Meeting here. Abstracts can also be found on the 2023 AASLD Liver Meeting website.

Mallinckrodt will also be present at the meeting with an interactive Medical Affairs booth in the exhibit hall (Location D2825) throughout the duration of the meeting.

Data collected in retrospective, pooled, database, or post hoc analyses may have errors or omissions. Outcomes may be influenced by therapies not evaluated in the study and the clinical/health economic outcomes may not be solely attributable to TERLIVAZ.

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) involving rapid reduction in kidney function[1] is an acute and life-threatening condition that occurs in people with advanced liver disease.[6] 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.[6] HRS involving rapid reduction in kidney function[1] is estimated to affect more than 35,000 Americans annually and rates of HRS hospitalizations are increasing.[7,8] 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.[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, 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®, 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 impact of Mallinckrodt's pending Chapter 11 cases; 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" 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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