Mallinckrodt Presents Results on Real World Treatment Patterns and Outcomes in Hospitalized Patients with Esophageal Variceal Hemorrhage and Liver Cirrhosis Treated with Terlipressin at the American College of Gastroenterology Annual Scientific Meeting

October 25, 2021

U.K., multicenter, retrospective medical chart review study showed terlipressin is commonly prescribed for esophageal variceal hemorrhage (EVH) in real world clinical practice

DUBLIN, Oct. 25, 2021 /PRNewswire/ -- Mallinckrodt plc, (OTCMKTS: MNKKQ) a global biopharmaceutical company, today announced results from a retrospective medical chart review study examining treatment patterns and outcomes in hospitalized patients with esophageal variceal hemorrhage (EVH) and liver cirrhosis treated with terlipressin. EVH is a major complication of cirrhosis and a leading cause of death in people with cirrhosis.[1] Results were presented at the American College of Gastroenterology Annual Scientific Meeting being held virtually and live in Las Vegas from October 22-27. The poster can be accessed here on the company's website.

Terlipressin is an investigational product and its safety and effectiveness have not yet been established by the U.S. Food and Drug Administration.

The retrospective medical chart review study assessed real world outcomes in 195 hospitalized adult patients across 18 hospitals in the U.K. (where terlipressin is approved and available) from January 1, 2016, through September 30, 2019. To be eligible for the analysis, patients had to be at least 18 years of age at hospital admission, be admitted within 24-36 hours after occurrence of EVH, had a history of liver cirrhosis, complete hospital information from admission to discharge and no prior history of EVH in three months. Data were collected from hospital admission up to 90 days post-discharge or until death using an electronic case report form.

Nearly all patients (n=192; 98.5 percent) in the analysis were treated with terlipressin within a day of hospital admission and the mean treatment duration was 4.3 days. The primary clinical outcome was control of bleeding within 36 hours and five days defined per Baveno V criteria, which define treatment failure as death or fresh hematemesis or nasogastric aspiration of ≥100 mL of fresh blood ≥two hours after the start of a specific drug treatment or therapeutic endoscopy, 3-g drop in hemoglobin within any 24-hour period if no transfusion is administered, and hypovolemic shock.[2,3]

The study found that, based on Baveno V criteria, 116 patients (59.5 percent) achieved an initial bleed control within 36 hours and 111 patients (56.9 percent) within five days. Of the patients who had an initial bleed control in 36 hours, rebleeding was observed in 47 patients (40.5 percent) within three days, 50 patients (43.1 percent) within five days and 53 patients (45.7 percent) within seven days. Of the patients who had an initial bleed control in five days, rebleeding was observed in 46 patients (41.4 percent) within three days, 48 patients (43.2 percent) within five days and 48 patients (43.2 percent) within seven days of the initial bleed control.

The study had limitations inherent to the retrospective nature of the study design, and data collected was limited to the information available and extracted from patient medical charts.

"It is critically important to expand our knowledge of evidence-based medicine for EVH, and investigational therapies like terlipressin, so that we can strive to address health outcomes for patients," said Kevin Moore, M.D., Ph.D., lead investigator and **principal clinical research fellow at the** UCL Institute of Liver and Digestive Health, Royal Free Hospital, University College London.

Terlipressin has previously been studied and approved by the National Health Service in the U.K. in this patient population, and scientific evidence of the published study was summarized in a Cochrane review.[4] Terlipressin is one of the accepted vasoactive therapies recommended by the European Association for the Study of the Liver guidelines, which recommends that vasoconstrictive therapy should be initiated as soon as acute variceal bleeding is suspected and before endoscopy.[5]

"Mallinckrodt is committed to understanding terlipressin's potential for patients suffering from complications of cirrhosis and continuing to build on the existing scientific research of terlipressin for the treatment of these complications[6]," said **Steven Romano, M.D., Executive Vice President and Chief Scientific Officer at Mallinckrodt.**

This study was sponsored by Mallinckrodt.

About Esophageal Variceal Hemorrhage (EVH)

Esophageal varices are abnormal dilations of veins in the lower part of the esophagus that may develop in patients with chronic liver damage, or cirrhosis.4 Bleeding, or hemorrhage from these varices, is a life-threatening complication and is a leading cause of death in people with cirrhosis.1,4

About Terlipressin
Terlipressin is a potent vasopressin analogue selective for V1 receptors. It is an investigational product in the U.S. and Canada as the safety and efficacy have not been established with, nor has approval been granted by, regulatory authorities in either country. Terlipressin is approved for use outside the U.S. and Canada.

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 and ophthalmology; immunotherapy and neonatal respiratory critical care therapies; analgesics 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 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
Tara DiFlumeri
Senior Vice President, Green Room Communications
908-577-4531
tara@greenroompr.com

Investor Relations
Daniel J. Speciale
Vice President, Finance and Investor Relations Officer
314-654-3638
daniel.speciale@mnk.com

Government Affairs
Derek Naten
Vice President, Government Affairs & Patient Advocacy
derek.naten@mnk.com

References

1 Seo YS, et al. Lack of difference among terlipressin, somatostatin and octreotide in the control of acute gastroesophageal varicel hemorrhage. *Hepatology*. 2014;60(3):954-963.

2 Ahn SY, Park SY, Tak WY, et al. Prospective validation of Baveno V definitions and criteria for failure to control bleeding in portal hypertension. *Hepatology*. 2015;61(3):1033-1040.

3 de Franchis R, Baveno VF. Revising consensus in portal hypertension: report of the Baveno V consensus workshop on methodology of diagnosis and therapy in portal hypertension. *J Hepatol*. 2010;53(4):762-768

4 Ioannou G, Doust J, Rockey DC. Terlipressin for acute esophageal variceal hemorrhage. *Cochrane Database Syst Rev*. 2003(1):CD002147.

5 The European Association for the Study of the Liver. EASL Clinical Practice Guidelines for the management of patients with decompensated cirrhosis. *J Hepatol* (2018). https://doi.org/10.1016/j.jhep.2018.03.024.

6 National Organization for Rare Disorders. Hepatorenal Syndrome. Available at: https://rarediseases.org/rare-diseases/hepatorenal-syndrome/. Accessed October 18, 2021.

View original content to download multimedia:https://www.prnewswire.com/news-releases/mallinckrodt-presents-results-on-real-world-treatment-patterns-and-outcomes-in-hospitalized-patients-with-esophageal-variceal-hemorrhage-and-liver-cirrhosis-treated-with-terlipressin-at-the-american-college-of-gastroenterology-ann-301407216.html

SOURCE Mallinckrodt plc