



Mallinckrodt Announces Real World Data on Hepatorenal Syndrome (HRS) and Acute Kidney Injury (AKI) in Patients with Liver Disease at The Liver Meeting Digital Experience

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Advancing American kidney health has been identified as a key public health priority by a 2019 Presidential Executive Order

U.S. data on HRS and AKI in patients with liver disease may help advance kidney health

DUBLIN, Nov. 16, 2020 /PRNewswire/ -- [Mallinckrodt plc](#), a global biopharmaceutical company, today announced findings from a large U.S. database review of patient profiles and outcomes of patients hospitalized with hepatorenal syndrome (HRS) and acute kidney injury (AKI). The descriptive data on HRS and AKI patients with liver disease may help advance kidney health, aligned with a recent U.S. Executive Order (No. 13879). Findings were presented during a poster presentation at The Liver Meeting Digital Experience, the annual meeting of the American Association for the Study of Liver Diseases (AASLD). The poster can be accessed [here](#) on the company's website.

HRS is a life-threatening complication that may occur in patients with advanced liver disease.¹ HRS is classified into two distinct types – hepatorenal syndrome type-1 and type-2.¹ Hepatorenal syndrome type 1 (HRS-1) is a rapidly progressive condition that leads to renal failure.¹ It is often a challenge to effectively diagnose in a timely manner due to its diagnosis of exclusion.²

The Premier Healthcare Database, a U.S. hospital-based database with over 1,000 contributing hospitals, was used to identify adult patients with an International Classification of Diseases diagnosis of HRS or AKI and liver cirrhosis in 2017 and 2018. A total of 54,945 patients met study inclusion criteria, including 13,061 patients in the HRS cohort and 41,884 in the AKI cohort. Majority of the patients (90.2 percent) in the HRS cohort also had an AKI diagnosis. Comparing the HRS and AKI cohorts, in-hospital mortality rates were 26.4 percent versus 9.1 percent, respectively.³ Hospice discharge rates and proportion discharged home or self-care were 19 percent and 21.4 percent in the HRS cohort and 6.9 percent and 39.2 percent in the AKI cohort. Between the HRS and AKI cohorts, the average hospital length of stay was 10.9 versus 8.1 days.³

"Hepatorenal syndrome is difficult to diagnose and typically met with high mortality rates if left untreated. Identifying the disease from a large national hospital database, although with limitations, is important as it enables us to understand national practice patterns and outcomes," said **Andrew Allegretti, M.D. MSc, Director of Critical Care Nephrology, Massachusetts General Hospital**. "The descriptive data from this study may help advance kidney health in line with a 2019 Executive Order and may help support future research to help identify healthcare resource utilization and costs in this population."

HRS-1 has a median survival time of approximately two weeks and greater than 80 percent mortality within three months if left untreated.^{2,4} At present, there are no drug therapies approved for the treatment of HRS-1 in the U.S. or Canada.⁵ HRS-1 is estimated to affect between 30,000 and 40,000 patients in the U.S. annually.^{6,7}

"The work of Dr. Allegretti and his team around hepatorenal syndrome, and more specifically HRS-1, helps us better understand this complex disease and the potential costs that may be associated with it," said **George Wan, Ph.D., MPH, Vice President, Global Head of Health Economics and Outcomes Research at Mallinckrodt Pharmaceuticals**.

The study was funded by Mallinckrodt.

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; 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.

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CAUTIONARY STATEMENTS RELATED TO FORWARD-LOOKING STATEMENTS

This release includes forward-looking statements with regard to the study described in this release, 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.

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¹ National Organization for Rare Disorders. Hepatorenal Syndrome. Available at: <https://rarediseases.org/rare-diseases/hepatorenal-syndrome/>. Accessed November 3, 2020.

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³ Allegretti A, Böing E, Ahn S, Zhou H, Jamil K, Cort S, Huang X. Hepatorenal syndrome and acute kidney injury in patients with liver disease: National practice patterns and outcomes from a large U.S. database. Poster presented at: The Liver Meeting Digital Experience; November 13-16, 2020; Boston, MA.

⁴ Colle I and Laterre PF. Hepatorenal syndrome: the clinical impact of vasoactive therapy. *Expert Review of Gastroenterology & Hepatology*. (2018) 12:2, 173-188, DOI: 10.1080/17474124.2018.1417034.

⁵ Boyer TD, Medicis JJ, Pappas SC, et al. A randomized, placebo-controlled, double-blind study to confirm the reversal of hepatorenal syndrome type 1 with terlipressin: the REVERSE trial design. *Open Access Journal of Clinical Trials* 2012:4. <https://www.dovepress.com/a-randomized-placebo-controlled-double-blind-study-to-confirm-the-reve-peer-reviewed-article-OAJCT>.

⁶ C Pant, B S Jani, M Desai, A Deshpande, Prashant Pandya, Ryan Taylor, R Gilroy, M Olyae. Hepatorenal syndrome in hospitalized patients with chronic liver disease: results from the Nationwide Inpatient Sample 2002–2012. *Journal of Investigative Medicine*. 2016;64:33–38.

⁷ United States Census Bureau: Quick Facts. Available at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Accessed November 3, 2020.

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