Mallinckrodt Confirms that U.S. Food and Drug Administration (FDA) Will Convene an Advisory Committee to Review Terlipressin for the Treatment of Patients with Hepatorenal Syndrome Type 1 (HRS-1)

July 7, 2020

- Advisory committee meeting scheduled for July 15, 2020 -

STAINES-UPON-THAMES, United Kingdom, July 7, 2020 /PRNewswire/ -- Mallinckrodt plc (NYSE: MNK), a global biopharmaceutical company, today announced that the Cardiovascular and Renal Drugs Advisory Committee of the U.S. Food and Drug Administration (FDA) will, as expected, hold a virtual meeting to review data on terlipressin, an investigational agent being evaluated for the treatment of hepatorenal syndrome type 1 (HRS-1). The company announced the FDA accepted for review its New Drug Application (NDA) for terlipressin in April.

HRS-1 is an acute and life-threatening syndrome involving acute kidney failure in people with cirrhosis.[1] The condition has a median survival time of approximately two weeks and greater than 80 percent mortality within three months if left untreated.[2,3] At present, there are no approved drug therapies for HRS-1 in the U.S.,[4] and it is estimated to affect between 30,000 and 40,000 patients in the U.S. annually.[5,6]

"We look forward to engaging the advisory committee panel in a robust discussion of the clinical evidence to support the safety and efficacy profile of terlipressin," said **Steven Romano, M.D., Executive Vice President and Chief Scientific Officer at Mallinckrodt**. "And we are extremely grateful to all the patients and healthcare professionals who made the data collection possible. If approved, we believe terlipressin has the potential to address a critical unmet need in HRS-1."

The terlipressin NDA is based, in part, on results from the Phase 3 CONFIRM trial, which was the largest-ever prospective study (n=300) conducted in patients with HRS-1, and the culmination of a sustained, 17-year effort to develop terlipressin for potential use in the U.S. and Canada. Initial results were presented at The Liver Meeting® 2019, the annual meeting of the American Association for the Study of Liver Diseases (AASLD).

About Terlipressin

Terlipressin is a potent vasopressin analogue selective for V1 receptors being investigated for the treatment of HRS-1 in the U.S. and Canada. It is an investigational product in these countries 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 the anticipated regulatory review process 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: 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

For Trade Media Inquiries
Caren Begun
Green Room Communications
201-396-8551

caren@greenroompr.com

For Financial/Dailies Media Inquiries
Ron Bartlett
H+K Strategies
Senior Vice President
813-545-2399
ron.bartlett@hkstrategies.com

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

References

[1] National Organization for Rare Disorders. Hepatorenal Syndrome. Available at: https://rarediseases.org/rare-diseases/hepatorenal-syndrome/. Accessed June 12, 2020.

[2] 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.

[3] Gines P, Sola E, Angeli P, et al. Hepatorenal syndrome. Nature Reviews. (2018) 4:23.

[4] 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.

[5] C Pant, B S Jani, M Desai, A Deshpande, Prashant Pandya, Ryan Taylor, R Gilroy, M Olyaee. 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.

[6] United States Census Bureau: Quick Facts. Available at: https://www.census.gov/quickfacts/fact/table/US/PST045218. Accessed June 12, 2020.

View original content to download multimedia:http://www.prnewswire.com/news-releases/mallinckrodt-confirms-that-us-food-and-drug-administration-fda-will-convene-an-advisory-committee-to-review-terlipressin-for-the-treatment-of-patients-with-hepatorenal-syndrome-type-1-hrs-1-301089164.html

SOURCE Mallinckrodt Pharmaceuticals