Mallinckrodt to Present Results from its Pivotal Phase 3 CONFIRM Study of Terlipressin in Patients with Hepatorenal Syndrome Type 1 (HRS-1) at The Liver Meeting® 2019

October 21, 2019

-- Late-breaker abstract, "A North American Randomized Controlled Trial (RCT) of Terlipressin plus Albumin for the Treatment of Hepatorenal Syndrome Type 1 (HRS-1)" --

STAINES-UPON-THAMES, United Kingdom, Oct. 21, 2019 /PRNewswire/ -- Mallinckrodt plc (NYSE: MNK), a global biopharmaceutical company, today announced it will present results from its pivotal Phase 3 CONFIRM study in a late-breaker session on Monday, Nov. 11 at 3:30 pm ET during The Liver Meeting® 2019, the annual meeting of the American Association for the Study of Liver Diseases (AASLD) in Boston.

"We are honored to be presenting our CONFIRM abstract at AASLD," said **Steven Romano, M.D., Executive Vice President and Chief Scientific Officer at Mallinckrodt**. "We are dedicated to developing potential treatments for patients with severe and critical conditions, including complications of advanced liver disease, such as hepatorenal syndrome type 1."

The CONFIRM clinical trial assessed the efficacy and safety of terlipressin in 300 adults with hepatorenal syndrome type 1 (HRS-1), an acute and life-threatening syndrome involving acute kidney failure in people with cirrhosis.[1] CONFIRM is the largest prospective trial ever conducted in this patient population. Mallinckrodt announced in August that the study met its primary endpoint of verified HRS-1 reversal (p=0.012). "Verified HRS-1 reversal" is a term denoting three components: renal function improvement, avoidance of dialysis and short-term survival.

The company plans to submit a New Drug Application to the U.S. Food and Drug Administration (FDA) in early 2020. Terlipressin is an investigational product and its safety and effectiveness have not yet been established by the FDA or Health Canada.

"HRS-1 is estimated to affect between 30,000 and 40,000 patients in the U.S.[2,3] annually. It is a rapidly progressing and devastating condition, and many patients don't live beyond a few weeks if left untreated,"[4,5] said presenting author **Florence Wong, MBBS, MD, FRACP, FRCPC, hepatologist at Toronto General Hospital, and professor of Medicine at the University of Toronto.** "I am encouraged by the results of the CONFIRM trial of terlipressin, which, if approved, may make a difference in this difficult-to-treat patient population and I look forward to sharing these results for the first time at AASLD."

HRS-1 has a very poor prognosis, with a median survival of less than two weeks and greater than 80 percent mortality within three months if left untreated.[4,5] At present, there are no approved drug therapies for HRS-1 in the U.S. or Canada.[6]

About the Pivotal Phase 3 CONFIRM Study (multi-center, randomized, placebo-controlled, double-blind trial in the U.S. and Canada):[7]

- The trial was designed to confirm efficacy and safety of terlipressin for the treatment of HRS-1
- CONFIRM is the largest prospective trial ever conducted (n=300) in HRS-1 patients
- Eligibility criteria included adults with liver cirrhosis and ascites with rapidly worsening renal function and no response to diuretics or albumin
- Subjects were randomized in a 2:1 ratio to receive terlipressin plus albumin (n=199) or placebo plus albumin (n=101)
- The primary endpoint of Verified HRS reversal was intended to evaluate renal function improvement, avoidance of dialysis and short-term survival

Find out more information about the CONFIRM trial here on the ClinicalTrials.gov website.

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. Terlipressin 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 and the study described in this release, including expectations with regard to future regulatory filings 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.

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[7] Data on file. Mallinckrodt ARD, Inc.

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