Mallinckrodt Submits New Drug Application to FDA for Terlipressin

Mallinckrodt has submitted its New Drug Application to the U.S. Food and Drug Administration (FDA) for terlipressin, which is being investigated for the treatment of hepatorenal syndrome type 1 (HRS-1), an acute and life-threatening syndrome involving acute kidney failure in people with cirrhosis.[1] At present, there are no approved drug therapies for HRS-1 in the U.S.[2] HRS-1 is estimated to affect between 30,000 and 40,000 patients in the U.S. annually.[3,4]

Terlipressin is an investigational agent and its safety and effectiveness have not yet been established by the FDA.

Mallinckrodt is grateful for and would like to sincerely thank the patients, caregivers and investigators who participated in our clinical trial.

To learn more, read the press release here.

References

[1] National Organization for Rare Disorders. Hepatorenal Syndrome. Available at: https://rarediseases.org/rare-diseases/hepatorenal-syndrome/. Accessed April 9, 2019.

[2] 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.

[3] 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. J Investig Med 2016;64:33–38.

[4] US Census 2018 https://www.census.gov/search-results.html?searchType=web&cssp=SERP&q=US population 2018, Accessed on August 6, 2019.