

**FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)**

Cardiovascular and Renal Drugs Advisory Committee (CRDAC) Meeting
July 15, 2020

AGENDA

The committee will discuss new drug application (NDA) 22231, terlipressin, lyophilized powder for solution for injection, submitted by Mallinckrodt Pharmaceuticals, for the proposed indication of treatment of hepatorenal syndrome Type 1.

9:00 a.m.	Call to Order and Introduction of Committee	Julia B. Lewis, MD Chairperson, CRDAC
9:05 a.m.	Conflict of Interest Statement	Joyce Yu, PharmD Designated Federal Officer, CRDAC
9:10 a.m.	FDA Opening Remarks	Aliza Thompson, MD, MS Deputy Director Division of Cardiology and Nephrology (DCN) Office of Cardiology, Hematology, Endocrinology and Nephrology (OCHEN) Office of New Drugs (OND), CDER, FDA
9:15 a.m.	APPLICANT PRESENTATIONS	Mallinckrodt Pharmaceuticals
	Introduction	Khurram Jamil, MD Vice President, Clinical Research in Hepatology Critical Care Division, Mallinckrodt
	Pathophysiology of HRS-1 and Rationale for Terlipressin	Michael P. Curry, MD Section Chief of Hepatology Beth Israel Deaconess Medical Center Harvard Medical School
	Efficacy	Khurram Jamil, MD
	Safety	Chris Pappas, MD, JD, FAASLD Clinical Hepatologist Consultant, Mallinckrodt
	Risk Management	Khurram Jamil, MD
	Benefit/Risk and Clinical Considerations	Arun Sanyal, MD Professor, Department of Internal Medicine Division of Gastroenterology, Hepatology and Nutrition Virginia Commonwealth University School of Medicine

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10:45 a.m. Clarifying Questions

11:15 a.m. **BREAK**

11:25 a.m. **FDA PRESENTATIONS**

Terlipressin for the Treatment of
Hepatorenal Syndrome Type 1

Rekha Kambhampati, MD, MHS
Medical Officer
DCN, OCHEN, OND, CDER, FDA

Tzu-Yun McDowell, PhD
Clinical Analyst
DCN, OCHEN, OND, CDER, FDA

12:10 p.m. Clarifying Questions

12:30 p.m. **LUNCH**

1:30 p.m. **OPEN PUBLIC HEARING**

2:30 p.m. Questions to the Committee/Committee
Discussion

3:15 p.m. **BREAK**

3:25 p.m. Questions to the Committee/Committee
Discussion (cont.)

5:00 p.m. **ADJOURNMENT**