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

Pulmonary-Allergy Drugs Advisory Committee *(PADAC) Meeting*
November 9, 2022

DRAFT AGENDA

The committee will discuss the request for Emergency Use Authorization 113, for sabizabulin oral capsule, a tubulin polymerization inhibitor, submitted by Veru Inc., for the treatment of SARS-CoV-2 infection in hospitalized patients with moderate to severe COVID-19 infection who are at high risk of acute respiratory distress syndrome. A focus of the discussion will include the treatment effect size in the context of the high placebo mortality rate, the limited size of the safety database, and identifying the proposed population.

9:00 a.m.	Call to Order and Introduction of Committee	**David H. Au, MD, MS** Chairperson, PADAC
9:10 a.m.	Conflict of Interest Statement	**Takyiah Stevenson, PharmD** Designated Federal Officer, PADAC
9:15 a.m.	FDA Opening Remarks	**Banu A. Karimi-Shah, MD** Deputy Director Division of Pulmonology, Allergy, and Critical Care (DPACC) Office of Immunology and Inflammation (OII) Office of New Drugs (OND), CDER, FDA
9:25 a.m.	**APPLICANT PRESENTATIONS**	**Veru Inc.**
	Introduction	**Mitchell Steiner, MD** Chief Executive Officer and Chief Medical Officer Veru Inc.
	Efficacy and Safety	**K. Gary Barnette, PhD** Chief Scientific Officer Veru Inc.
	Sensitivity Analysis	**Lee-Jen Wei, PhD** Professor of Biostatistics Harvard University, T.H. Chan School of Public Health

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DRAFT AGENDA (cont.)

	APPLICANT PRESENTATIONS (cont.)	
	Benefit/Risk Assessment	**Christian Sandrock, MD, MPH** Division Vice Chief of Internal Medicine and Director of Critical Care University of California, Davis, School of Medicine
	Concluding Remarks	**Mitchell Steiner, MD**
10:45 a.m.	Clarifying Questions to the Applicant	
11:10 a.m.	**BREAK**	
11:20 a.m.	**FDA PRESENTATIONS**	
	Overview of the Clinical Program and Review of Safety	**Robert Busch, MD, MMSc** Medical Officer DPACC, OII, OND, CDER, FDA
	Statistical Review of Efficacy	**Sai Dharmarajan, PhD** Senior Mathematical Statistician Division of Biometrics VII Office of Biostatistics, Office of Translational Science CDER, FDA
	Uncertainties and Clinical Considerations	**Robert Busch, MD, MMSc** **Sai Dharmarajan, PhD**
12:30 p.m.	Clarifying questions for FDA	
12:45 p.m.	**LUNCH**	
1:30 p.m.	**OPEN PUBLIC HEARING**	
2:30 p.m.	Charge to the Committee	**Banu A. Karimi-Shah, MD**

DRAFT AGENDA (cont.)

2:45 p.m.	Questions to the Committee/Committee Discussion
3:20 p.m.	**BREAK**
3:30 p.m.	Questions to the Committee/Committee Discussion (cont.)
5:00 p.m.	**ADJOURNMENT**