

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

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

AGENDA

The committee will discuss the request for Emergency Use Authorization 113, for sibuzabulin 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	David H. Au, MD, MS Chairperson, PADAC
9:10 a.m.	Introduction of Committee and 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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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

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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**