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

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

**QUESTIONS**

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1. **DISCUSSION:** Discuss the strength of the all-cause mortality data, specifically considering the uncertainties raised by the Agency in Study 902, including the high observed placebo mortality rate, potential for unblinding, differences in standard of care before and during the trial, differences in timing of enrollment, potential differences in goals of care decision-making, and defining the studied population.

2. **DISCUSSION**: Discuss your level of concern regarding the limited size of the safety database for this new molecular entity.

3. **VOTE**: Do the known and potential benefits of VERU-111 when used for the treatment of adult patients hospitalized with COVID-19 at high risk of ARDS outweigh the known and potential risks of VERU-111?

    a. If yes, discuss the appropriate patient population in which VERU-111 should be authorized.
    b. If no, discuss what additional data would be necessary to assess the benefits vs. the risks of treatment.

4. **DISCUSSION:** If authorized, the Agency believes that additional data are necessary to understand the benefit-risk assessment as a condition of authorization. Please discuss the proposed design aspects of a study to provide this additional data.