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

Pulmonary-Allergy Drugs Advisory Committee (PADAC) Meeting
May 11, 2023

DRAFT QUESTIONS

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1. **DISCUSSION:** Discuss the pharmacokinetic/pharmacodynamic (PK/PD) approach for establishing efficacy for ARS-1 (epinephrine nasal spray) for the emergency treatment of allergic reactions (Type I) including anaphylaxis, specifically:

    a. The PK-bracketing approach using approved epinephrine injection products.

    b. The relevant PK/PD parameters to support clinical efficacy for the intended indication, including the significance of the following findings:

        - The diminished PK/PD sustainability in subjects with allergen-induced nasal congestion compared to epinephrine injection products and lack of data from repeat dosing under allergen-induced nasal congestion conditions.

        - The different comparisons of single-dose ARS-1 and Adrenalin in the first 10 minutes for Study EPI 15, EPI 16 (without allergen-induced nasal congestion), and EPI 17.

    c. The uncertainty of translation of PK/PD results from healthy subjects and subjects with allergen-induced nasal congestion to patients with anaphylaxis, and whether clinical data are needed.

2. **VOTE**: Do the PK/PD results support a favorable benefit-risk assessment for ARS-1 in adults for the emergency treatment of allergic reactions (Type I) and anaphylaxis?

    a. If not, what additional data are needed?

3. **VOTE**: Do the PK/PD results support a favorable benefit-risk assessment for ARS-1 in children (<18 years of age) ≥30 kg for the emergency treatment of allergic reactions (Type I) and anaphylaxis?

    a. If not, what additional data are needed?