Introduction

- Respiratory Syncytial Virus (RSV) infection causes significant morbidity/mortality, especially in newborns.
- Airway obstruction by secretions can lead to hypoxia, apnea, need for supplemental oxygen (e.g., mechanical ventilation), hospitalization, and death.
- RSV infection also linked with risk of asthma later in life.
- No effective RSV treatment or vaccine exists.

Study Design

**Key Entry Criteria**

- Confirmed RSV positive (BINAX NOW (study-provided), polymerase chain reaction (PCR), etc.)
- Requires invasive mechanical ventilation
- Requires chronic medications

Assessments

- **Pharmacokinetics (PK)**: In SAD, 8 subjects in each age stratum (≤6 mo, >6 mo to <12 months, ≥12 months)
- To determine if ALS-008176 exposure results in the emergence of resistant strains of RSV

**Results**

- **Subjects Dosed, Dose Levels**
  - Single Dose (N=9) N=24 (3 ALS-8176-1 Placebo subjects per cohort)
  - Multiple Dose (N=42) N=24 (3 ALS-8176-1 Placebo subjects per cohort)

- **Baseline Characteristics**
  - Age (months) - Mean (SD)
  - White
  - Asian
  - Mixed Race/Other
  - Weight (kg) - Mean (SD)

- **TEAEs**
  - Serious TEAEs reported
  - TEAEs leading to discontinuation

**Conclusions**

- **Interim results from this ongoing blinded study in otherwise healthy infants hospitalized with RSV infection demonstrate that single and multiple ALS-8176 doses up to 25 mg/kg and 30 mg/kg, respectively, are well tolerated.
- **Monitor EPS data are consistent with predictions of the observed PK data on multiple occasions and has recommended that the study continue to advance with no changes in planned conduct**.

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