A Pilot Phase 2a, Randomized, Double-blind, Placebo-controlled Study to Explore the Antiviral Activity, Clinical Outcomes, Safety and Tolerability Levels of Rilematovir at Two Dose Levels in Non-hospitalized Adults Infected with Respiratory Syncytial Virus (RSV)

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Introduction

- Respiratory syncytial virus (RSV) causes a substantial burden in adults, including those in the community setting, and can be severe in certain at-risk groups, particularly older adults (aged ≥65 years), and those with underlying cardiovascular or pulmonary comorbidities such as chronic obstructive pulmonary disease (COPD) or asthma.
- Despite the high disease burden, there is a lack of efficacious direct-acting antiviral therapies to treat adults with RSV infection; management options are currently limited and supportive.
- Therefore, there is a need for additional therapies to treat adults with RSV infection.

Study Methods

- **Study Design:** This was a Phase 2a, randomized, double-blind, multicenter, placebo-controlled study in non-hospitalized adults aged 18–79 years with diagnosis of RSV infection within 5–7 days of symptom onset (Figure 1).

Study Assessments

- **Study Assessments:** For categorical variables, frequency tables were presented. For continuous variables, descriptive statistics (n, mean, standard deviation [SD], median) were provided.

Data Analysis

- **Study Data:**
  - There was no clear effect of rilematovir versus placebo on VL over time for both mean VL AUC and change from baseline analyses.
  - Most baseline demographics were similar among treatment groups (Table 1).
  - Symptoms, including those at high risk of severe disease, demonstrated antiviral effect based on reduction in time to undetectability of nasal RSV VL and favorable impact on clinical effect based on reduction in time to undetectability of nasal RSV VL and favorable impact on clinical outcomes (Figure 3).

Conclusions

- **Conclusions:** The sample size of patients with any risk factor for severe RSV was too small to make a reliable conclusion about the treatment effect of rilematovir in this group.
- This study provides proof-of-concept and warrants further investigation of rilematovir in places with access to these high-risk adults.

References


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Disclosures