# Protocol 004 CLEVER All-Cause Endpoints

| All-cause Endpoint *(Through 5 months Postdose)* | Clesrovimab (N = 2,411) | | | | Placebo (N = 1,203) | | | | Observed Efficacy (%) Estimate (95% CI)[c] |
|---|---|---|---|---|---|---|---|---|---|
| | n | Number of Events | Total Follow-Up Time (months)[a] | Incidence Rate Over 5 months[b], % | n | Number of Events | Total Follow-Up Time (months)[a] | Incidence Rate over 5 months[b], % | |
| **Outpatient and Inpatient MALRI due to any cause** | 2,398 | 526 | 10,349.2 | 25.4 | 1,201 | 296 | 5,063.8 | 29.2 | 13.1 (-0.6; 24.8) |
| **LRI Hospitalization due to any cause** | 2,398 | 60 | 11,711.8 | 2.6 | 1,201 | 58 | 5,774.0 | 5.0 | 49.0 (26.7, 64.5) |

a. One month is defined as 30 days for the total follow-up time calculation; b. Five months is defined as 150 days; c. Estimate and 95% CI of efficacy were estimated from the modified Poisson regression with robust variance method; Every participant is counted a single time for each applicable endpoint category; A participant may appear in more than one endpoint category; For each participant, only the first occurrence of the case for each endpoint category is counted for the analysis; N=Number of participants randomized and dosed with clesrovimab or placebo; n=Number of participants eligible for inclusion in the full analysis set population; CI=Confidence Interval; LRI=Lower Respiratory Tract Infection; MALRI=Medically-Attended Lower Respiratory Tract Infection.

Sinha A. Safety and Efficacy of Clesrovimab. CDC, ACIP Presentation Slides Oct 23-24, 2024 Meeting 02-RSV-Mat-Peds-Sinha-508.pdf (cdc.gov)