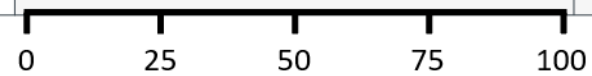
PN004 CLEVER Efficacy Summary, Days 1–150[1,2]

RSV-associated Endpoint	Endpoint Designation	Efficacy through 5 months (150 days)			
		Clesrovimab (n=2,398) # of Cases	Placebo (n=1,201) # of Cases	Observed Efficacy %, (95% CI) [a]	Pre-Specified Hypothesis
Severe MALRI	Tertiary	2	12	91.7 (62.9, 98.1)	
LRI Hospitalization	Tertiary	5	27	90.9 (76.2, 96.5)	
Hospitalization	Secondary	9	28	84.2 (66.6, 92.6)	*P*<0.001
MALRI requiring ≥2 Indicators of LRI/Severity[b]	Post-Hoc	10	41	88.0 (76.1, 94.0)	
MALRI requiring ≥1 Indicator of LRI/Severity	Primary	60	74	60.4 (44.1, 71.9)	*P*<0.001
Acute Respiratory Infection (ARI)	Tertiary	148	148	52.0 (39.5, 61.9)	

Increasing Disease Severity



A single dose of clesrovimab was efficacious against mild, moderate, and severe RSV disease in healthy preterm and full-term infants through 5 months

ARI=Acute Respiratory Infection; LRI=Lower Respiratory Tract Infection; MALRI=Medically-Attended Lower Respiratory Tract Infection.
ARI and MALRI include both inpatient and outpatient cases; Full Analysis Set Population. Primary endpoint criterion=lower bound of the 95% CI >25%; Secondary endpoint criterion=lower bound of the 95% CI >0%)
[a] Estimate and 95% CI of efficacy were estimated from the modified Poisson regression with robust variance method [b]Endpoint comparable to nirsevimab's primary endpoint in the MELODY trial
1. Zar HJ, Simoes EAF, Madhi SA et al. A Phase 2b/3 Study to Evaluate the Efficacy and Safety of an Investigational Respiratory Syncytial Virus (RSV) Antibody, Clesrovimab, in Healthy Preterm and Full-Term Infants. Oral Presentation. *Infectious Diseases Society of America (IDSA)* 2024; 2. 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)