PN007 SMART Incidence of RSV-associated Endpoints Season 1 (Days 1–150) [1,2]

RSV-associated endpoint	Clesrovimab n=443			Palivizumab n=437		
	Number of events	Total follow-up time (months)[a]	Incidence rate, % over 5 months[b] (95% CI)[c]	Number of events	Total follow-up time (months)[a]	Incidence rate, % over 5 months[b] (95% CI)[c]
MALRI requiring ≥1 indicator of LRI or severity[d]	14	1946.9	**3.6%** (2.0, 6.0)	12	1969.5	**3.0%** (1.6, 5.3)
Hospitalization[e]	5	1968.9	**1.3%** (0.4, 3.0)	6	1987.3	**1.5%** (0.6, 3.3)

Note: Incidence rates in Protocol 007 are similar through 6 months postdose

CI, confidence interval. LRI, lower respiratory infection. MALRI, medically attended lower respiratory infection, both inpatient and outpatient cases. n, number of participants eligible for inclusion in the full analysis set population.
[a]One month was defined as 30 days. [b]Five months were defined as 150 days. [c]Confidence intervals were estimated by exact Poisson confidence limits. [d]Defined as: RSV PCR positive and cough or difficulty breathing and at least 1 of the following: wheezing, chest wall indrawing/retractions, rales/crackles, hypoxemia, tachypnea, or dehydration due to respiratory symptoms. [e]Hospitalization defined as: RSV PCR positive and hospital admission for respiratory illness.
1. Zar HJ, Bont LJ, Manzoni P et al. Phase 3, Randomized, Controlled Trial Evaluating Safety, Efficacy, and Pharmacokinetics of Clesrovimab in Infants and Children at Increased Risk for Severe Respiratory Syncytial Virus Disease. 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)