

Table 2. Safety Summary

	Clesrovimab					Placebo
	20 mg, n (%)	50 mg, n (%)	75 mg, n (%)	100 mg Preterm, n (%)	100 mg Full-Term, n (%)	
Participants	6	33	40	32	32	38
≥1 AE	6 (100.0)	27 (81.8)	33 (82.5)	26 (81.3)	27 (84.4)	33 (86.8)
Solicited injection-site AEs ^{a,b}	3 (50.0)	3 (9.1)	3 (7.5)	2 (6.3)	2 (6.3)	2 (5.3)
Injection-site erythema ^{a,b}	1 (16.7)	2 (6.1)	1 (2.5)	1 (3.1)	1 (3.1)	1 (2.6)
Injection-site pain ^{a,b}	2 (33.3)	0 (0.0)	2 (5.0)	2 (6.3)	0 (0.0)	1 (2.6)
Injection-site swelling ^{a,b}	2 (33.3)	1 (3.0)	0 (0.0)	0 (0.0)	1 (3.1)	1 (2.6)
Solicited systemic AEs ^{a,b}	2 (33.3)	8 (24.4)	9 (22.5)	2 (6.3)	3 (9.4)	9 (23.7)
Appetite loss ^{a,b}	1 (16.7)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)
Drowsiness ^{a,b}	1 (16.7)	2 (6.1)	5 (12.5)	1 (3.1)	1 (3.1)	3 (7.9)
Fever ^{a,b}	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.1)	0 (0.0)	0 (0.0)
Irritability ^{a,b}	2 (33.3)	5 (15.2)	5 (12.5)	2 (6.3)	2 (6.3)	9 (23.7)
Treatment-related AEs ^c	3 (50.0)	9 (27.3)	11 (27.5)	4 (12.5)	8 (25.0)	7 (18.4)
SAEs	1 (16.7)	4 (12.1)	1 (2.5)	3 (9.4)	6 (18.8)	6 (15.8)
Treatment-related SAEs ^c	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Solicited allergic reactions	0 (0.0)	1 (3.0)	2 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Treatment-related solicited allergic reactions ^c	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

All participants as treated population. Nonserious AEs were collected from day 1 to day 14 postdose, solicited AEs of allergic reactions were collected from day 1 to day 30 postdose, respiratory adverse events were collected from day 1 to day 365 postdose, and SAEs were collected from day 1 throughout the study duration.

Abbreviations: AE, adverse event; SAE, serious adverse event.

^aSolicited injection-site and solicited systemic adverse events were collected days 1–5 postdose.

^bEvery participant is counted a single time for each applicable row and column.

^cDetermined by investigator to be related to treatment.