

Table S5: Unsolicited AEs through 28 Days of the Final Vaccination by MedDRA SOC, PT, and Maximum Reported Severity

	Placebo (N=12) n (%)				20 µg (N=18) n (%)				100 µg (N=18) n (%)				Overall (N=48) n (%)
MedDRA SOC/PT	Any	Gr 1	Gr 2	Gr 3	Any	Gr 1	Gr 2	Gr 3	Any	Gr 1	Gr 2	Gr 3	Any
Any AE	11 (91.7)	7 (58.3)	3 (25.0)	1 (8.3)	15 (83.3)	9 (50.0)	4 (22.2)	2 (11.1)	10 (55.6)	6 (33.3)	4 (22.2)	0 (0.0)	36 (75.0)
Infections and infestations	6 (50.0)	4 (33.3)	1 (8.3)	1 (8.3)	9 (50.0)	6 (33.3)	2 (11.1)	1 (5.6)	4 (22.2)	2 (11.1)	2 (11.1)	0 (0.0)	19 (39.6)
Upper respiratory tract infection	6 (50.0)	4 (33.3)	1 (8.3)	1 (8.3)	5 (27.8)	3 (16.7)	1 (5.6)	1 (5.6)	3 (16.7)	2 (11.1)	1 (5.6)	0 (0.0)	14 (29.2)
Rhinitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Conjunctivitis	1 (8.3)	1 (8.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Cystitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Hordeolum	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Lyme disease	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	1 (5.6)	0 (0.0)	1 (2.1)
Viral infection	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Gastrointestinal disorders	3 (25.0)	2 (16.7)	1 (8.3)	0 (0.0)	5 (27.8)	5 (27.8)	0 (0.0)	0 (0.0)	3 (16.7)	3 (16.7)	0 (0.0)	0 (0.0)	11 (22.9)
Paraesthesia oral	3 (25.0)	3 (25.0)	0 (0.0)	0 (0.0)	3 (16.7)	3 (16.7)	0 (0.0)	0 (0.0)	3 (16.7)	3 (16.7)	0 (0.0)	0 (0.0)	9 (18.8)
Diarrhoea	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Dyspepsia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Gastroesophageal reflux disease	1 (8.3)	0 (0.0)	1 (8.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Nervous system disorders	2 (16.7)	2 (16.7)	0 (0.0)	0 (0.0)	4 (22.2)	3 (16.7)	1 (5.6)	0 (0.0)	2 (11.1)	1 (5.6)	1 (5.6)	0 (0.0)	8 (16.7)
Headache	2 (16.7)	2 (16.7)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (6.3)
Dizziness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	1 (5.6)	0 (0.0)	0 (0.0)	1 (2.1)
Hypoaesthesia	1 (8.3)	1 (8.3)	0 (0.0)	0 (0.0)	1 (5.6)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.2)
Presyncope	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	1 (5.6)	0 (0.0)	0 (0.0)	1 (5.6)	1 (5.6)	0 (0.0)	0 (0.0)	2 (4.2)
Disturbance in attention	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Tension headache	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	1 (5.6)	0 (0.0)	1 (2.1)
Musculoskeletal and connective tissue disorders	4 (33.3)	3 (25.0)	1 (8.3)	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	1 (5.6)	2 (11.1)	1 (5.6)	1 (5.6)	0 (0.0)	7 (14.6)
Musculoskeletal chest pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Musculoskeletal pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Plantar fasciitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	1 (5.6)	0 (0.0)	1 (2.1)
General disorders and administration site conditions	1 (8.3)	1 (8.3)	0 (0.0)	0 (0.0)	3 (16.7)	3 (16.7)	0 (0.0)	0 (0.0)	2 (11.1)	1 (5.6)	1 (5.6)	0 (0.0)	6 (12.5)
Fatigue	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	1 (5.6)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	1 (5.6)	0 (0.0)	2 (4.2)
Axillary pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Feeling hot	1 (8.3)	1 (8.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)

Table S5 continued, 2 of 5

MedDRA SOC/PT	Placebo (N=12) n (%)				20 µg (N=18) n (%)				100 µg (N=18) n (%)				Overall (N=48) n (%)
	Any	Gr 1	Gr 2	Gr 3	Any	Gr 1	Gr 2	Gr 3	Any	Gr 1	Gr 2	Gr 3	Any
Hangover	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Non-cardiac chest pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	1 (5.6)	0 (0.0)	0 (0.0)	1 (2.1)
Injury, poisoning and procedural complications	1 (8.3)	1 (8.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (16.7)	2 (11.1)	1 (5.6)	0 (0.0)	4 (8.3)
Muscle strain	1 (8.3)	1 (8.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Animal bite	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	1 (5.6)	0 (0.0)	0 (0.0)	1 (2.1)
Ear injury	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	1 (5.6)	0 (0.0)	0 (0.0)	1 (2.1)
Foot fracture	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	1 (5.6)	0 (0.0)	1 (2.1)
Respiratory, thoracic and mediastinal disorders	1 (8.3)	1 (8.3)	0 (0.0)	0 (0.0)	2 (11.1)	1 (5.6)	1 (5.6)	0 (0.0)	1 (5.6)	1 (5.6)	0 (0.0)	0 (0.0)	4 (8.3)
Oropharyngeal pain	1 (8.3)	1 (8.3)	0 (0.0)	0 (0.0)	1 (5.6)	1 (5.6)	0 (0.0)	0 (0.0)	1 (5.6)	1 (5.6)	0 (0.0)	0 (0.0)	3 (6.3)
Nasal congestion	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Blood and lymphatic system disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (16.7)	3 (16.7)	0 (0.0)	0 (0.0)	3 (6.3)
Anaemia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (11.1)	2 (11.1)	0 (0.0)	0 (0.0)	2 (4.2)
Lymphadenopathy	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	1 (5.6)	0 (0.0)	0 (0.0)	1 (2.1)
Psychiatric disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Anxiety	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Depression	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Reproductive system and breast disorders	1 (8.3)	0 (0.0)	1 (8.3)	0 (0.0)	1 (5.6)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.2)
Intermenstrual bleeding	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Uterine spasm	1 (8.3)	0 (0.0)	1 (8.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Vascular disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	1 (5.6)	0 (0.0)	0 (0.0)	1 (5.6)	1 (5.6)	0 (0.0)	0 (0.0)	2 (4.2)
Haematoma	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Hypotension	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	1 (5.6)	0 (0.0)	0 (0.0)	1 (2.1)
Metabolism and nutrition disorders	1 (8.3)	0 (0.0)	1 (8.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Decreased appetite	1 (8.3)	0 (0.0)	1 (8.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)

N = Total number of volunteers in the safety analysis population per group

n = For the 'Any' columns, cells present the number of volunteers with at least one event (volunteers with >1 reported event are counted only once). For the by grade columns, cells present the number of volunteers with at least one event at the maximum reported severity (volunteers with >1 reported event are counted only once and only at the maximum reported severity).

% = Percentage of volunteers in each category, i.e., $100 \times n/N$

Gr = Grade Maximum reported severity over all events was grade 3.

MedDRA = Medical Dictionary for Regulatory Activities

SOC = System Organ Class

PT = Preferred Terms

MedDRA SOCs and PTs within SOCs are presented by descending overall frequency of volunteers with an event.

Unsolicited AEs are presented through 28 days after the final vaccination.