Table S6: Unsolicited AEs Related to Study Procedure 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 | 4 (33.3) | 4 (33.3) | 0 | 0 | 6 (33.3) | 6 (33.3) | 0 | 0 | 5 (27.8) | 5 (27.8) | 0 | 0 | 15 (31.3) |
| Gastrointestinal  disorders | 3 (25.0) | 3 (25.0) | 0 | 0 | 3 (16.7) | 3 (16.7) | 0 | 0 | 3 (16.7) | 3 (16.7) | 0 | 0 | 9 (18.8) |
| Paraesthesia oral | 3 (25.0) | 3 (25.0) | 0 | 0 | 3 (16.7) | 3 (16.7) | 0 | 0 | 3 (16.7) | 3 (16.7) | 0 | 0 | 9 (18.8) |
| Nervous system disorders | 1 (8.3) | 1 (8.3) | 0 | 0 | 2 (11.1) | 2 (11.1) | 0 | 0 | 2 (11.1) | 2 (11.1) | 0 | 0 | 5 (10.4) |
| Dizziness | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (5.6) | 1 (5.6) | 0 | 0 | 1 (2.1) |
| Hypoaesthesia | 1 (8.3) | 1 (8.3) | 0 | 0 | 1 (5.6) | 1 (5.6) | 0 | 0 | 0 | 0 | 0 | 0 | 2 (4.2) |
| Presyncope | 0 | 0 | 0 | 0 | 1 (5.6) | 1 (5.6) | 0 | 0 | 1 (5.6) | 1 (5.6) | 0 | 0 | 2 (4.2) |
| Vascular disorders | 0 | 0 | 0 | 0 | 1 (5.6) | 1 (5.6) | 0 | 0 | 1 (5.6) | 1 (5.6) | 0 | 0 | 2 (4.2) |
| Haematoma | 0 | 0 | 0 | 0 | 1 (5.6) | 1 (5.6) | 0 | 0 | 0 | 0 | 0 | 0 | 1 (2.1) |
| Hypotension | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (5.6) | 1 (5.6) | 0 | 0 | 1 (2.1) |
| Blood and lymphatic  system disorders | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (5.6) | 1 (5.6) | 0 | 0 | 1 (2.1) |
| Lymphadenopathy | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (5.6) | 1 (5.6) | 0 | 0 | 1 (2.1) |
| General disorders and  administration site conditions | 0 | 0 | 0 | 0 | 1 (5.6) | 1 (5.6) | 0 | 0 | 0 | 0 | 0 | 0 | 1 (2.1) |
| Axillary pain | 0 | 0 | 0 | 0 | 1 (5.6) | 1 (5.6) | 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 x n/N  
Gr = Grade*

*MedDRA = Medical Dictionary for Regulatory Activities*

*SOC = System Organ Class*

*PT = Preferred Terms  
Maximum reported severity over all events was grade 1.  
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.  
'Related' is defined as possibly, probably, or definitely related to Study Procedure.*