

THE LANCET

Supplementary appendix

This appendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

Supplement to: Manning JE, Oliveira F, Countinho-Abreu IV, et al. Safety and immunogenicity of a mosquito saliva peptide-based vaccine: a randomised, placebo-controlled, double-blind, phase 1 trial. *Lancet* 2020; published online June 11. [https://doi.org/10.1016/S0140-6736\(20\)31048-5](https://doi.org/10.1016/S0140-6736(20)31048-5).

Supplemental Table 1: Structure and Physical Properties of the AGS-v peptides

| | AGS-6 Acetate | AGS-30 Acetate | AGS-31 Acetate | AGS-35 Acetate |
|---------------------------------|--|--|--|--|
| Size (mer) | 33 | 44 | 36 | 32 |
| Molecular Formula | C ₁₆₄ H ₂₆₄ N ₅₀ O ₄₆ S ₃ | C ₂₁₄ H ₃₅₇ N ₆₁ O ₅₈ S ₄ | C ₁₈₂ H ₃₀₅ N ₆₁ O ₅₄ | C ₁₅₄ H ₂₄₃ N ₄₁ O ₅₄ S ₄ |
| Molecular Mass | 3768.4 Da | 4840.8 Da | 4211.8 Da | 3661.1 Da |
| Amino Acid Sequence | H-Lys-Gln-Asn-Asp-Tyr-Gln-Ala-Leu-Leu-Gly-Leu-Cys-Cys-Pro-Trp-Ile-Asp-Leu-Ala-Ala-Ala-Asp-Leu-Pro-Met-Arg-Arg-His-Ala-Lys-Ala-Arg-Glu-OH, acetate salt | H-Ala-Leu-Val-Leu-His-Ser-Met-Leu-Val-Asn-Ala-Ser-Leu-Ala-Glu-Met-Val-Lys-Glu-Ser-Tyr-Gln-Thr-His-Gly-Ala-Asp-Gly-Arg-Met-Val-Val-Arg-Met-Leu-Lys-Phe-Val-Arg-Leu-Leu-Pro-Gly-Ala-OH, acetate salt | H-Val-Gln-Arg-Val-Arg-Ala-Leu-Arg-Ala-Leu-Leu-Glu-Thr-Leu-Leu-Gln-His-Gln-Gly-Glu-Gln-Asn-Asn-Asp-Val-Tyr-Leu-Ile-Arg-Leu-Ala-His-Glu-Thr-Gly-Arg-OH, acetate salt | H-His-Asp-Gln-Tyr-Ser-Met-Glu-Cys-Leu-Glu-Ala-Ala-Glu-Pro-Lys-Tyr-Leu-Asp-Gly-Leu-Lys-Thr-Leu-Ala-Asp-Glu-Thr-Ala-Gln-Cys-Met-Arg-OH, acetate salt |
| Source Protein Name | Salivary gland 7-like protein | Salivary gland 1-like protein | Salivary gland 1-like protein | gSG7 protein |
| Source Protein Accession Number | AAL68786.1 | AAL68784.1 | AAL68784.1 | CAC35523.1 |

Supplemental Table 2. Adverse Events Summary

Table 1 : Summary of Max Grade Adverse Events Per Subject

| Event | Adjuvant + AGS-V (N = 17) | | | | | | AGS-V (N = 16) | | | | | | Placebo (N = 16) | | | | | |
|--------------------------------------|---------------------------|---------|---------------|---------------|--------------|--------------|----------------|---------|---------------|--------------|--------------|--------------|------------------|---------|--------------|--------------|---------------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Abdominal cramps | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Abdominal pain | 14 (82.35%) | 0 (0%) | 3 (17.65%) | 0 (0%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Absolute neutrophil count, decreased | 15 (88.24%) | 0 (0%) | 2 (11.76%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) |
| Acute sinusitis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| ALT increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 13 (81.25%) | 0 (0%) | 3 (18.75%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Anxiety | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Arthralgia | 14 (82.35%) | 0 (0%) | 1 (5.88%) | 2 (11.76%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| AST increased | 15 (88.24%) | 0 (0%) | 2 (11.76%) | 0 (0%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Bilirubin total high | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Blood eosinophils increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Bradycardia | 16 (94.12%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| BUN increased | 15 (88.24%) | 0 (0%) | 1 (5.88%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Campylobacter | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Candida vaginitis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Chills | 14 (82.35%) | 0 (0%) | 0 (0%) | 3 (17.65%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Common cold | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Constipation | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Coryza | 15 (88.24%) | 0 (0%) | 1 (5.88%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| CPK increased | 12 (70.59%) | 0 (0%) | 0 (0%) | 3 (17.65%) | 1 (5.88%) | 1 (5.88%) | 14 (87.5%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 1 (6.25%) | 10 (62.5%) | 0 (0%) | 1 (6.25%) | 2 (12.5%) | 3 (18.75%) | 0 (0%) |

| Event | Adjuvant + AGS-V (N = 17) | | | | | | AGS-V (N = 16) | | | | | | Placebo (N = 16) | | | | | |
|---------------------------|---------------------------|---------|-------------|------------|-----------|---------|----------------|---------|-------------|-----------|-----------|---------|------------------|---------|-------------|-----------|-----------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Creatine kinase | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| Creatine kinase high | 16 (94.12%) | 0 (0%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) |
| Creatinine increased | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Dermatitis | 16 (94.12%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Diaphoresis | 15 (88.24%) | 0 (0%) | 1 (5.88%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Diarrhea | 15 (88.24%) | 0 (0%) | 1 (5.88%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Difficulty sleeping | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Dry cough | 15 (88.24%) | 0 (0%) | 2 (11.76%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Eczema | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Elevated liver enzymes | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Elevated serum creatinine | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Eosinophilia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Erythema | 2 (11.76%) | 0 (0%) | 14 (82.35%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Eyelid Stye | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Fatigue | 9 (52.94%) | 0 (0%) | 5 (29.41%) | 3 (17.65%) | 0 (0%) | 0 (0%) | 11 (68.75%) | 0 (0%) | 5 (31.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 12 (75%) | 0 (0%) | 3 (18.75%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| Fever | 16 (94.12%) | 0 (0%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Feverish | 10 (58.82%) | 0 (0%) | 4 (23.53%) | 3 (17.65%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 13 (81.25%) | 0 (0%) | 3 (18.75%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Gastritis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Headache | 9 (52.94%) | 0 (0%) | 4 (23.53%) | 4 (23.53%) | 0 (0%) | 0 (0%) | 9 (56.25%) | 0 (0%) | 5 (31.25%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 12 (75%) | 0 (0%) | 4 (25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hematuria | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 13 (81.25%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 13 (81.25%) | 0 (0%) | 1 (6.25%) | 2 (12.5%) | 0 (0%) | 0 (0%) |
| Hemoglobin decreased | 10 (58.82%) | 0 (0%) | 6 (35.29%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 8 (50%) | 0 (0%) | 4 (25%) | 4 (25%) | 0 (0%) | 0 (0%) | 11 (68.75%) | 0 (0%) | 4 (25%) | 1 (6.25%) | 0 (0%) | 0 (0%) |

| Event | Adjuvant + AGS-V (N = 17) | | | | | | AGS-V (N = 16) | | | | | | Placebo (N = 16) | | | | | |
|---------------------------|---------------------------|-----------|-------------|------------|------------|---------|----------------|-----------|-------------|------------|-----------|---------|------------------|-----------|-------------|-----------|-----------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Hyperglycemia | 16 (94.12%) | 0 (0%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) |
| Hypertremia | 14 (82.35%) | 0 (0%) | 2 (11.76%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 12 (75%) | 0 (0%) | 3 (18.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 13 (81.25%) | 0 (0%) | 2 (12.5%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| Hypertension | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypocalcemia | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypoglycemia | 14 (82.35%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 2 (11.76%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) | 13 (81.25%) | 0 (0%) | 1 (6.25%) | 1 (6.25%) | 1 (6.25%) | 0 (0%) |
| Hypokalemia | 15 (88.24%) | 0 (0%) | 1 (5.88%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 1 (6.25%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 13 (81.25%) | 0 (0%) | 1 (6.25%) | 1 (6.25%) | 1 (6.25%) | 0 (0%) |
| Hyponatremia | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypophosphatemia | 16 (94.12%) | 0 (0%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 12 (75%) | 0 (0%) | 1 (6.25%) | 3 (18.75%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 1 (6.25%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| Influenza | 16 (94.12%) | 0 (0%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site erythema | 9 (52.94%) | 1 (5.88%) | 3 (17.65%) | 3 (17.65%) | 1 (5.88%) | 0 (0%) | 13 (81.25%) | 2 (12.5%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 1 (6.25%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site induration | 15 (88.24%) | 1 (5.88%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site itching | 10 (58.82%) | 0 (0%) | 6 (35.29%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site pain | 8 (47.06%) | 0 (0%) | 7 (41.18%) | 2 (11.76%) | 0 (0%) | 0 (0%) | 10 (62.5%) | 0 (0%) | 6 (37.5%) | 0 (0%) | 0 (0%) | 0 (0%) | 12 (75%) | 0 (0%) | 3 (18.75%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| Injection site pruritus | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site swelling | 8 (47.06%) | 1 (5.88%) | 7 (41.18%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injury | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Insect bite | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Iron deficiency anemia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Knee pain | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Laryngitis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Local swelling | 1 (5.88%) | 0 (0%) | 16 (94.12%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Adjuvant + AGS-V (N = 17) | | | | | | AGS-V (N = 16) | | | | | | Placebo (N = 16) | | | | | |
|----------------------------|---------------------------|---------|------------|-----------|-----------|---------|----------------|---------|------------|-----------|---------|---------|------------------|---------|-----------|-----------|-----------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Lymph node tenderness | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Lymphocyte count increased | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Muscle ache | 15 (88.24%) | 0 (0%) | 2 (11.76%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Muscle strain | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Myalgia | 12 (70.59%) | 0 (0%) | 4 (23.53%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 13 (81.25%) | 0 (0%) | 2 (12.5%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 11 (68.75%) | 0 (0%) | 4 (25%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| Nasal congestion | 15 (88.24%) | 0 (0%) | 2 (11.76%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Nausea | 15 (88.24%) | 0 (0%) | 2 (11.76%) | 0 (0%) | 0 (0%) | 0 (0%) | 13 (81.25%) | 0 (0%) | 2 (12.5%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Neutrophil count decreased | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 12 (75%) | 0 (0%) | 3 (18.75%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 13 (81.25%) | 0 (0%) | 2 (12.5%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| Oral pain | 16 (94.12%) | 0 (0%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Peripheral neuropathy | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Productive cough | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Pruritic rash | 15 (88.24%) | 0 (0%) | 0 (0%) | 1 (5.88%) | 1 (5.88%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Pruritus | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Rash | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 13 (81.25%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 1 (6.25%) | 0 (0%) |
| Rhinorrhea | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Sinusitis | 16 (94.12%) | 0 (0%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Skin hyperpigmentation | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Skin induration | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Sore throat | 15 (88.24%) | 0 (0%) | 1 (5.88%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Systolic hypertension | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Tenderness | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Adjuvant + AGS-V (N = 17) | | | | | | AGS-V (N = 16) | | | | | | Placebo (N = 16) | | | | | |
|-----------------------------------|---------------------------|---------|-----------|-----------|-----------|---------|----------------|---------|-----------|-----------|-----------|---------|------------------|---------|-----------|-----------|-----------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Tooth extraction | 16 (94.12%) | 0 (0%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Torn bicep tendon | 16 (94.12%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Upper respiratory tract infection | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urinary frequency | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urinary tract infection | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) |
| Urine WBC increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urticaria | 16 (94.12%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Vertigo | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) |
| Vitamin D deficiency | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Vomiting | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 1 (6.25%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| WBC decreased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 1 (6.25%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| WBC increased | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |

Table 2 : Counts of Adverse Events by Treatment Group

| | Adjuvant + AGS-V (N = 17) | AGS-V (N = 16) | Placebo (N = 16) |
|--|---------------------------|--------------------|-------------------|
| Number of Subjects with one or more AE (percent) | 17 (100%) | 16 (100%) | 15 (93.8%) |
| Mean Number of AEs (SD, SE) | 14.82 (8.81, 2.14) | 11.38 (6.51, 1.63) | 9.81 (6.25, 1.56) |
| Median Number of AEs (IQR) | 13 (10) | 10 (11.25) | 10 (9.5) |
| Min, Max Number of AEs | 4, 33 | 2, 21 | 0, 22 |
| Number of Subjects with one or more AE Grade 3 or Higher (percent) | 7 (41%) | 6 (38%) | 7 (44%) |
| Mean Number of AEs Grade 3 or Higher | 0.65 (0.93, 0.23) | 0.44 (0.63, 0.16) | 0.63 (0.89, 0.22) |

Table 3 : Occurrence of Grade 0 Events by Treatment Group**Note : In Tables 3-7, multiple occurrences of the same event type with different grades are included in the respective table**

| Event | Adjuvant + AGS-V (N = 17) | AGS-V (N = 16) | Placebo (N = 16) |
|--------------------------------------|----------------------------------|-----------------------|-------------------------|
| Abdominal cramps | 0 (0%) | 0 (0%) | 0 (0%) |
| Abdominal pain | 0 (0%) | 0 (0%) | 0 (0%) |
| Absolute neutrophil count, decreased | 0 (0%) | 0 (0%) | 0 (0%) |
| Acute sinusitis | 0 (0%) | 0 (0%) | 0 (0%) |
| ALT increased | 0 (0%) | 0 (0%) | 0 (0%) |
| Anxiety | 0 (0%) | 0 (0%) | 0 (0%) |
| Arthralgia | 0 (0%) | 0 (0%) | 0 (0%) |
| AST increased | 0 (0%) | 0 (0%) | 0 (0%) |
| Bilirubin total high | 0 (0%) | 0 (0%) | 0 (0%) |
| Blood eosinophils increased | 0 (0%) | 0 (0%) | 0 (0%) |
| Bradycardia | 0 (0%) | 0 (0%) | 0 (0%) |
| BUN increased | 0 (0%) | 0 (0%) | 0 (0%) |
| Campylobacter | 0 (0%) | 0 (0%) | 0 (0%) |
| Candida vaginitis | 0 (0%) | 0 (0%) | 0 (0%) |
| Chills | 0 (0%) | 0 (0%) | 0 (0%) |
| Common cold | 0 (0%) | 0 (0%) | 0 (0%) |
| Constipation | 0 (0%) | 0 (0%) | 0 (0%) |
| Coryza | 0 (0%) | 0 (0%) | 0 (0%) |
| CPK increased | 0 (0%) | 0 (0%) | 0 (0%) |
| Creatine kinase | 0 (0%) | 0 (0%) | 0 (0%) |
| Creatine kinase high | 0 (0%) | 0 (0%) | 0 (0%) |
| Creatinine increased | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Adjuvant + AGS-V (N = 17) | AGS-V (N = 16) | Placebo (N = 16) |
|---------------------------|----------------------------------|-----------------------|-------------------------|
| Dermatitis | 0 (0%) | 0 (0%) | 0 (0%) |
| Diaphoresis | 0 (0%) | 0 (0%) | 0 (0%) |
| Diarrhea | 0 (0%) | 0 (0%) | 0 (0%) |
| Difficulty sleeping | 0 (0%) | 0 (0%) | 0 (0%) |
| Dry cough | 0 (0%) | 0 (0%) | 0 (0%) |
| Eczema | 0 (0%) | 0 (0%) | 0 (0%) |
| Elevated liver enzymes | 0 (0%) | 0 (0%) | 0 (0%) |
| Elevated serum creatinine | 0 (0%) | 0 (0%) | 0 (0%) |
| Eosinophilia | 0 (0%) | 0 (0%) | 0 (0%) |
| Erythema | 0 (0%) | 0 (0%) | 0 (0%) |
| Eyelid Stye | 0 (0%) | 0 (0%) | 0 (0%) |
| Fatigue | 0 (0%) | 0 (0%) | 0 (0%) |
| Fever | 0 (0%) | 0 (0%) | 0 (0%) |
| Feverish | 0 (0%) | 0 (0%) | 0 (0%) |
| Gastritis | 0 (0%) | 0 (0%) | 0 (0%) |
| Headache | 0 (0%) | 0 (0%) | 0 (0%) |
| Hematuria | 0 (0%) | 0 (0%) | 0 (0%) |
| Hemoglobin decreased | 0 (0%) | 0 (0%) | 0 (0%) |
| Hyperglycemia | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypernatremia | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypertension | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypocalcemia | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypoglycemia | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypokalemia | 0 (0%) | 0 (0%) | 0 (0%) |
| Hyponatremia | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypophosphatemia | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Adjuvant + AGS-V (N = 17) | AGS-V (N = 16) | Placebo (N = 16) |
|----------------------------|----------------------------------|-----------------------|-------------------------|
| Influenza | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site erythema | 3 (17.65%) | 3 (18.75%) | 1 (6.25%) |
| Injection site induration | 1 (5.88%) | 0 (0%) | 0 (0%) |
| Injection site itching | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site pain | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site pruritus | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site swelling | 2 (11.76%) | 2 (12.5%) | 1 (6.25%) |
| Injury | 0 (0%) | 0 (0%) | 0 (0%) |
| Insect bite | 0 (0%) | 0 (0%) | 0 (0%) |
| Iron deficiency anemia | 0 (0%) | 0 (0%) | 0 (0%) |
| Knee pain | 0 (0%) | 0 (0%) | 0 (0%) |
| Laryngitis | 0 (0%) | 0 (0%) | 0 (0%) |
| Local swelling | 0 (0%) | 0 (0%) | 0 (0%) |
| Lymph node tenderness | 0 (0%) | 0 (0%) | 0 (0%) |
| Lymphocyte count increased | 0 (0%) | 0 (0%) | 0 (0%) |
| Muscle ache | 0 (0%) | 0 (0%) | 0 (0%) |
| Muscle strain | 0 (0%) | 0 (0%) | 0 (0%) |
| Myalgia | 0 (0%) | 0 (0%) | 0 (0%) |
| Nasal congestion | 0 (0%) | 0 (0%) | 0 (0%) |
| Nausea | 0 (0%) | 0 (0%) | 0 (0%) |
| Neutrophil count decreased | 0 (0%) | 0 (0%) | 0 (0%) |
| Oral pain | 0 (0%) | 0 (0%) | 0 (0%) |
| Peripheral neuropathy | 0 (0%) | 0 (0%) | 0 (0%) |
| Productive cough | 0 (0%) | 0 (0%) | 0 (0%) |
| Pruritic rash | 0 (0%) | 0 (0%) | 0 (0%) |
| Pruritus | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Adjuvant + AGS-V (N = 17) | AGS-V (N = 16) | Placebo (N = 16) |
|-----------------------------------|----------------------------------|-----------------------|-------------------------|
| Rash | 0 (0%) | 0 (0%) | 0 (0%) |
| Rhinorrhea | 0 (0%) | 0 (0%) | 0 (0%) |
| Sinusitis | 0 (0%) | 0 (0%) | 0 (0%) |
| Skin hyperpigmentation | 0 (0%) | 0 (0%) | 0 (0%) |
| Skin induration | 0 (0%) | 0 (0%) | 0 (0%) |
| Sore throat | 0 (0%) | 0 (0%) | 0 (0%) |
| Systolic hypertension | 0 (0%) | 0 (0%) | 0 (0%) |
| Tenderness | 0 (0%) | 0 (0%) | 0 (0%) |
| Tooth extraction | 0 (0%) | 0 (0%) | 0 (0%) |
| Torn bicep tendon | 0 (0%) | 0 (0%) | 0 (0%) |
| Upper respiratory tract infection | 0 (0%) | 0 (0%) | 0 (0%) |
| Urinary frequency | 0 (0%) | 0 (0%) | 0 (0%) |
| Urinary tract infection | 0 (0%) | 0 (0%) | 0 (0%) |
| Urine WBC increased | 0 (0%) | 0 (0%) | 0 (0%) |
| Urticaria | 0 (0%) | 0 (0%) | 0 (0%) |
| Vertigo | 0 (0%) | 0 (0%) | 0 (0%) |
| Vitamin D deficiency | 0 (0%) | 0 (0%) | 0 (0%) |
| Vomiting | 0 (0%) | 0 (0%) | 0 (0%) |
| WBC decreased | 0 (0%) | 0 (0%) | 0 (0%) |
| WBC increased | 0 (0%) | 0 (0%) | 0 (0%) |

Table 4 : Occurrence of Grade 1 Events by Treatment Group

| Event | Adjuvant + AGS-V (N = 17) | AGS-V (N = 16) | Placebo (N = 16) |
|--------------------------------------|----------------------------------|-----------------------|-------------------------|
| Abdominal cramps | 0 (0%) | 1 (6.25%) | 0 (0%) |
| Abdominal pain | 3 (17.65%) | 2 (12.5%) | 1 (6.25%) |
| Absolute neutrophil count, decreased | 2 (11.76%) | 1 (6.25%) | 1 (6.25%) |
| Acute sinusitis | 0 (0%) | 0 (0%) | 1 (6.25%) |

| Event | Adjuvant + AGS-V (N = 17) | AGS-V (N = 16) | Placebo (N = 16) |
|-----------------------------|----------------------------------|-----------------------|-------------------------|
| ALT increased | 0 (0%) | 3 (18.75%) | 0 (0%) |
| Anxiety | 0 (0%) | 1 (6.25%) | 0 (0%) |
| Arthralgia | 2 (11.76%) | 1 (6.25%) | 0 (0%) |
| AST increased | 2 (11.76%) | 2 (12.5%) | 1 (6.25%) |
| Bilirubin total high | 0 (0%) | 1 (6.25%) | 0 (0%) |
| Blood eosinophils increased | 0 (0%) | 1 (6.25%) | 0 (0%) |
| Bradycardia | 1 (5.88%) | 1 (6.25%) | 0 (0%) |
| BUN increased | 2 (11.76%) | 0 (0%) | 1 (6.25%) |
| Campylobacter | 0 (0%) | 0 (0%) | 1 (6.25%) |
| Candida vaginitis | 0 (0%) | 0 (0%) | 2 (12.5%) |
| Chills | 1 (5.88%) | 2 (12.5%) | 1 (6.25%) |
| Common cold | 1 (5.88%) | 0 (0%) | 1 (6.25%) |
| Constipation | 0 (0%) | 0 (0%) | 1 (6.25%) |
| Coryza | 1 (5.88%) | 0 (0%) | 1 (6.25%) |
| CPK increased | 2 (11.76%) | 0 (0%) | 4 (25%) |
| Creatine kinase | 0 (0%) | 0 (0%) | 0 (0%) |
| Creatine kinase high | 1 (5.88%) | 0 (0%) | 0 (0%) |
| Creatinine increased | 1 (5.88%) | 0 (0%) | 0 (0%) |
| Dermatitis | 0 (0%) | 0 (0%) | 0 (0%) |
| Diaphoresis | 1 (5.88%) | 2 (12.5%) | 1 (6.25%) |
| Diarrhea | 1 (5.88%) | 0 (0%) | 1 (6.25%) |
| Difficulty sleeping | 1 (5.88%) | 0 (0%) | 0 (0%) |
| Dry cough | 2 (11.76%) | 0 (0%) | 0 (0%) |
| Eczema | 1 (5.88%) | 0 (0%) | 0 (0%) |
| Elevated liver enzymes | 1 (5.88%) | 0 (0%) | 0 (0%) |
| Elevated serum creatinine | 1 (5.88%) | 0 (0%) | 0 (0%) |

| Event | Adjuvant + AGS-V (N = 17) | AGS-V (N = 16) | Placebo (N = 16) |
|---------------------------|----------------------------------|-----------------------|-------------------------|
| Eosinophilia | 0 (0%) | 1 (6.25%) | 0 (0%) |
| Erythema | 15 (88.24%) | 15 (93.75%) | 15 (93.75%) |
| Eyelid Stye | 0 (0%) | 1 (6.25%) | 0 (0%) |
| Fatigue | 8 (47.06%) | 5 (31.25%) | 4 (25%) |
| Fever | 0 (0%) | 0 (0%) | 2 (12.5%) |
| Feverish | 5 (29.41%) | 1 (6.25%) | 3 (18.75%) |
| Gastritis | 0 (0%) | 0 (0%) | 1 (6.25%) |
| Headache | 7 (41.18%) | 6 (37.5%) | 4 (25%) |
| Hematuria | 1 (5.88%) | 1 (6.25%) | 2 (12.5%) |
| Hemoglobin decreased | 7 (41.18%) | 8 (50%) | 5 (31.25%) |
| Hyperglycemia | 0 (0%) | 2 (12.5%) | 1 (6.25%) |
| Hypernatremia | 2 (11.76%) | 4 (25%) | 2 (12.5%) |
| Hypertension | 1 (5.88%) | 0 (0%) | 0 (0%) |
| Hypocalcemia | 1 (5.88%) | 1 (6.25%) | 0 (0%) |
| Hypoglycemia | 2 (11.76%) | 2 (12.5%) | 2 (12.5%) |
| Hypokalemia | 1 (5.88%) | 1 (6.25%) | 1 (6.25%) |
| Hyponatremia | 1 (5.88%) | 0 (0%) | 0 (0%) |
| Hypophosphatemia | 1 (5.88%) | 2 (12.5%) | 2 (12.5%) |
| Influenza | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site erythema | 5 (29.41%) | 1 (6.25%) | 1 (6.25%) |
| Injection site induration | 1 (5.88%) | 0 (0%) | 0 (0%) |
| Injection site itching | 6 (35.29%) | 1 (6.25%) | 0 (0%) |
| Injection site pain | 9 (52.94%) | 6 (37.5%) | 4 (25%) |
| Injection site pruritus | 0 (0%) | 2 (12.5%) | 0 (0%) |
| Injection site swelling | 8 (47.06%) | 0 (0%) | 0 (0%) |
| Injury | 0 (0%) | 1 (6.25%) | 0 (0%) |

| Event | Adjuvant + AGS-V (N = 17) | AGS-V (N = 16) | Placebo (N = 16) |
|----------------------------|----------------------------------|-----------------------|-------------------------|
| Insect bite | 0 (0%) | 0 (0%) | 1 (6.25%) |
| Iron deficiency anemia | 0 (0%) | 0 (0%) | 0 (0%) |
| Knee pain | 1 (5.88%) | 0 (0%) | 0 (0%) |
| Laryngitis | 0 (0%) | 0 (0%) | 1 (6.25%) |
| Local swelling | 16 (94.12%) | 15 (93.75%) | 15 (93.75%) |
| Lymph node tenderness | 1 (5.88%) | 0 (0%) | 0 (0%) |
| Lymphocyte count increased | 1 (5.88%) | 0 (0%) | 0 (0%) |
| Muscle ache | 2 (11.76%) | 0 (0%) | 0 (0%) |
| Muscle strain | 1 (5.88%) | 0 (0%) | 0 (0%) |
| Myalgia | 5 (29.41%) | 3 (18.75%) | 5 (31.25%) |
| Nasal congestion | 2 (11.76%) | 1 (6.25%) | 1 (6.25%) |
| Nausea | 2 (11.76%) | 3 (18.75%) | 2 (12.5%) |
| Neutrophil count decreased | 1 (5.88%) | 4 (25%) | 2 (12.5%) |
| Oral pain | 0 (0%) | 0 (0%) | 0 (0%) |
| Peripheral neuropathy | 0 (0%) | 0 (0%) | 1 (6.25%) |
| Productive cough | 1 (5.88%) | 0 (0%) | 0 (0%) |
| Pruritic rash | 0 (0%) | 1 (6.25%) | 0 (0%) |
| Pruritus | 1 (5.88%) | 0 (0%) | 0 (0%) |
| Rash | 0 (0%) | 0 (0%) | 2 (12.5%) |
| Rhinorrhea | 1 (5.88%) | 0 (0%) | 1 (6.25%) |
| Sinusitis | 0 (0%) | 0 (0%) | 0 (0%) |
| Skin hyperpigmentation | 1 (5.88%) | 1 (6.25%) | 0 (0%) |
| Skin induration | 1 (5.88%) | 0 (0%) | 0 (0%) |
| Sore throat | 2 (11.76%) | 1 (6.25%) | 1 (6.25%) |
| Systolic hypertension | 0 (0%) | 1 (6.25%) | 0 (0%) |
| Tenderness | 1 (5.88%) | 0 (0%) | 0 (0%) |

| Event | Adjuvant + AGS-V (N = 17) | AGS-V (N = 16) | Placebo (N = 16) |
|-----------------------------------|----------------------------------|-----------------------|-------------------------|
| Tooth extraction | 0 (0%) | 0 (0%) | 0 (0%) |
| Torn bicep tendon | 0 (0%) | 0 (0%) | 0 (0%) |
| Upper respiratory tract infection | 0 (0%) | 1 (6.25%) | 0 (0%) |
| Urinary frequency | 0 (0%) | 0 (0%) | 1 (6.25%) |
| Urinary tract infection | 0 (0%) | 0 (0%) | 0 (0%) |
| Urine WBC increased | 0 (0%) | 2 (12.5%) | 0 (0%) |
| Urticaria | 0 (0%) | 0 (0%) | 0 (0%) |
| Vertigo | 0 (0%) | 0 (0%) | 0 (0%) |
| Vitamin D deficiency | 1 (5.88%) | 0 (0%) | 0 (0%) |
| Vomiting | 0 (0%) | 1 (6.25%) | 0 (0%) |
| WBC decreased | 0 (0%) | 0 (0%) | 2 (12.5%) |
| WBC increased | 1 (5.88%) | 2 (12.5%) | 1 (6.25%) |

Table 5 : Occurrence of Grade 2 Events by Treatment Group

| Event | Adjuvant + AGS-V (N = 17) | AGS-V (N = 16) | Placebo (N = 16) |
|--------------------------------------|----------------------------------|-----------------------|-------------------------|
| Abdominal cramps | 0 (0%) | 0 (0%) | 0 (0%) |
| Abdominal pain | 0 (0%) | 0 (0%) | 0 (0%) |
| Absolute neutrophil count, decreased | 0 (0%) | 1 (6.25%) | 1 (6.25%) |
| Acute sinusitis | 0 (0%) | 0 (0%) | 0 (0%) |
| ALT increased | 0 (0%) | 0 (0%) | 0 (0%) |
| Anxiety | 0 (0%) | 0 (0%) | 0 (0%) |
| Arthralgia | 2 (11.76%) | 0 (0%) | 0 (0%) |
| AST increased | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Adjuvant + AGS-V (N = 17) | AGS-V (N = 16) | Placebo (N = 16) |
|-----------------------------|----------------------------------|-----------------------|-------------------------|
| Bilirubin total high | 0 (0%) | 0 (0%) | 0 (0%) |
| Blood eosinophils increased | 0 (0%) | 0 (0%) | 0 (0%) |
| Bradycardia | 0 (0%) | 0 (0%) | 0 (0%) |
| BUN increased | 1 (5.88%) | 0 (0%) | 0 (0%) |
| Campylobacter | 0 (0%) | 0 (0%) | 0 (0%) |
| Candida vaginitis | 0 (0%) | 0 (0%) | 0 (0%) |
| Chills | 3 (17.65%) | 0 (0%) | 0 (0%) |
| Common cold | 0 (0%) | 0 (0%) | 0 (0%) |
| Constipation | 0 (0%) | 0 (0%) | 0 (0%) |
| Coryza | 1 (5.88%) | 0 (0%) | 0 (0%) |
| CPK increased | 5 (29.41%) | 2 (12.5%) | 4 (25%) |
| Creatine kinase | 0 (0%) | 0 (0%) | 1 (6.25%) |
| Creatine kinase high | 1 (5.88%) | 1 (6.25%) | 0 (0%) |
| Creatinine increased | 0 (0%) | 0 (0%) | 0 (0%) |
| Dermatitis | 0 (0%) | 0 (0%) | 0 (0%) |
| Diaphoresis | 1 (5.88%) | 0 (0%) | 0 (0%) |
| Diarrhea | 1 (5.88%) | 0 (0%) | 0 (0%) |
| Difficulty sleeping | 0 (0%) | 0 (0%) | 0 (0%) |
| Dry cough | 0 (0%) | 0 (0%) | 0 (0%) |
| Eczema | 0 (0%) | 0 (0%) | 0 (0%) |
| Elevated liver enzymes | 0 (0%) | 0 (0%) | 0 (0%) |
| Elevated serum creatinine | 0 (0%) | 0 (0%) | 0 (0%) |
| Eosinophilia | 0 (0%) | 0 (0%) | 0 (0%) |
| Erythema | 1 (5.88%) | 0 (0%) | 0 (0%) |
| Eyelid Sty | 0 (0%) | 0 (0%) | 0 (0%) |
| Fatigue | 3 (17.65%) | 0 (0%) | 1 (6.25%) |

| Event | Adjuvant + AGS-V (N = 17) | AGS-V (N = 16) | Placebo (N = 16) |
|---------------------------|----------------------------------|-----------------------|-------------------------|
| Fever | 1 (5.88%) | 0 (0%) | 0 (0%) |
| Feverish | 3 (17.65%) | 0 (0%) | 0 (0%) |
| Gastritis | 0 (0%) | 0 (0%) | 0 (0%) |
| Headache | 4 (23.53%) | 2 (12.5%) | 0 (0%) |
| Hematuria | 0 (0%) | 0 (0%) | 2 (12.5%) |
| Hemoglobin decreased | 1 (5.88%) | 4 (25%) | 1 (6.25%) |
| Hyperglycemia | 1 (5.88%) | 2 (12.5%) | 2 (12.5%) |
| Hypernatremia | 1 (5.88%) | 0 (0%) | 1 (6.25%) |
| Hypertension | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypocalcemia | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypoglycemia | 1 (5.88%) | 0 (0%) | 2 (12.5%) |
| Hypokalemia | 1 (5.88%) | 1 (6.25%) | 1 (6.25%) |
| Hyponatremia | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypophosphatemia | 1 (5.88%) | 3 (18.75%) | 1 (6.25%) |
| Influenza | 1 (5.88%) | 0 (0%) | 0 (0%) |
| Injection site erythema | 4 (23.53%) | 0 (0%) | 0 (0%) |
| Injection site induration | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site itching | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site pain | 2 (11.76%) | 0 (0%) | 1 (6.25%) |
| Injection site pruritus | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site swelling | 1 (5.88%) | 0 (0%) | 0 (0%) |
| Injury | 0 (0%) | 0 (0%) | 0 (0%) |
| Insect bite | 0 (0%) | 0 (0%) | 0 (0%) |
| Iron deficiency anemia | 0 (0%) | 1 (6.25%) | 0 (0%) |
| Knee pain | 0 (0%) | 0 (0%) | 0 (0%) |
| Laryngitis | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Adjuvant + AGS-V (N = 17) | AGS-V (N = 16) | Placebo (N = 16) |
|-----------------------------------|----------------------------------|-----------------------|-------------------------|
| Local swelling | 0 (0%) | 0 (0%) | 0 (0%) |
| Lymph node tenderness | 0 (0%) | 0 (0%) | 0 (0%) |
| Lymphocyte count increased | 0 (0%) | 0 (0%) | 0 (0%) |
| Muscle ache | 0 (0%) | 0 (0%) | 0 (0%) |
| Muscle strain | 0 (0%) | 0 (0%) | 0 (0%) |
| Myalgia | 1 (5.88%) | 1 (6.25%) | 1 (6.25%) |
| Nasal congestion | 0 (0%) | 0 (0%) | 0 (0%) |
| Nausea | 0 (0%) | 1 (6.25%) | 0 (0%) |
| Neutrophil count decreased | 0 (0%) | 1 (6.25%) | 1 (6.25%) |
| Oral pain | 1 (5.88%) | 0 (0%) | 0 (0%) |
| Peripheral neuropathy | 0 (0%) | 0 (0%) | 0 (0%) |
| Productive cough | 0 (0%) | 0 (0%) | 0 (0%) |
| Pruritic rash | 1 (5.88%) | 0 (0%) | 0 (0%) |
| Pruritus | 0 (0%) | 0 (0%) | 0 (0%) |
| Rash | 0 (0%) | 0 (0%) | 0 (0%) |
| Rhinorrhea | 0 (0%) | 0 (0%) | 0 (0%) |
| Sinusitis | 1 (5.88%) | 0 (0%) | 0 (0%) |
| Skin hyperpigmentation | 0 (0%) | 0 (0%) | 0 (0%) |
| Skin induration | 0 (0%) | 0 (0%) | 0 (0%) |
| Sore throat | 1 (5.88%) | 1 (6.25%) | 0 (0%) |
| Systolic hypertension | 0 (0%) | 0 (0%) | 0 (0%) |
| Tenderness | 0 (0%) | 0 (0%) | 0 (0%) |
| Tooth extraction | 1 (5.88%) | 0 (0%) | 0 (0%) |
| Torn bicep tendon | 0 (0%) | 0 (0%) | 0 (0%) |
| Upper respiratory tract infection | 0 (0%) | 0 (0%) | 0 (0%) |
| Urinary frequency | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Adjuvant + AGS-V (N = 17) | AGS-V (N = 16) | Placebo (N = 16) |
|-------------------------|----------------------------------|-----------------------|-------------------------|
| Urinary tract infection | 0 (0%) | 0 (0%) | 0 (0%) |
| Urine WBC increased | 0 (0%) | 0 (0%) | 0 (0%) |
| Urticaria | 0 (0%) | 0 (0%) | 0 (0%) |
| Vertigo | 0 (0%) | 0 (0%) | 0 (0%) |
| Vitamin D deficiency | 0 (0%) | 0 (0%) | 0 (0%) |
| Vomiting | 0 (0%) | 1 (6.25%) | 0 (0%) |
| WBC decreased | 0 (0%) | 0 (0%) | 1 (6.25%) |
| WBC increased | 0 (0%) | 0 (0%) | 0 (0%) |

Table 6 : Occurrence of Grade 3 Events by Treatment Group

| Event | Adjuvant + AGS-V (N = 17) | AGS-V (N = 16) | Placebo (N = 16) |
|--------------------------------------|----------------------------------|-----------------------|-------------------------|
| Abdominal cramps | 0 (0%) | 0 (0%) | 0 (0%) |
| Abdominal pain | 0 (0%) | 0 (0%) | 0 (0%) |
| Absolute neutrophil count, decreased | 0 (0%) | 1 (6.25%) | 1 (6.25%) |
| Acute sinusitis | 0 (0%) | 0 (0%) | 0 (0%) |
| ALT increased | 0 (0%) | 0 (0%) | 0 (0%) |
| Anxiety | 0 (0%) | 0 (0%) | 0 (0%) |
| Arthralgia | 0 (0%) | 0 (0%) | 0 (0%) |
| AST increased | 0 (0%) | 0 (0%) | 0 (0%) |
| Bilirubin total high | 0 (0%) | 0 (0%) | 0 (0%) |
| Blood eosinophils increased | 0 (0%) | 0 (0%) | 0 (0%) |
| Bradycardia | 1 (5.88%) | 0 (0%) | 0 (0%) |
| BUN increased | 0 (0%) | 0 (0%) | 0 (0%) |
| Campylobacter | 0 (0%) | 0 (0%) | 0 (0%) |
| Candida vaginitis | 0 (0%) | 0 (0%) | 0 (0%) |
| Chills | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Adjuvant + AGS-V (N = 17) | AGS-V (N = 16) | Placebo (N = 16) |
|---------------------------|----------------------------------|-----------------------|-------------------------|
| Common cold | 0 (0%) | 0 (0%) | 0 (0%) |
| Constipation | 0 (0%) | 0 (0%) | 0 (0%) |
| Coryza | 0 (0%) | 0 (0%) | 0 (0%) |
| CPK increased | 1 (5.88%) | 0 (0%) | 3 (18.75%) |
| Creatine kinase | 0 (0%) | 0 (0%) | 0 (0%) |
| Creatine kinase high | 0 (0%) | 0 (0%) | 1 (6.25%) |
| Creatinine increased | 0 (0%) | 0 (0%) | 0 (0%) |
| Dermatitis | 1 (5.88%) | 0 (0%) | 0 (0%) |
| Diaphoresis | 0 (0%) | 0 (0%) | 0 (0%) |
| Diarrhea | 0 (0%) | 0 (0%) | 0 (0%) |
| Difficulty sleeping | 0 (0%) | 0 (0%) | 0 (0%) |
| Dry cough | 0 (0%) | 0 (0%) | 0 (0%) |
| Eczema | 0 (0%) | 0 (0%) | 0 (0%) |
| Elevated liver enzymes | 0 (0%) | 0 (0%) | 0 (0%) |
| Elevated serum creatinine | 0 (0%) | 0 (0%) | 0 (0%) |
| Eosinophilia | 0 (0%) | 0 (0%) | 0 (0%) |
| Erythema | 0 (0%) | 0 (0%) | 0 (0%) |
| Eyelid Stye | 0 (0%) | 0 (0%) | 0 (0%) |
| Fatigue | 0 (0%) | 0 (0%) | 0 (0%) |
| Fever | 0 (0%) | 0 (0%) | 0 (0%) |
| Feverish | 0 (0%) | 0 (0%) | 0 (0%) |
| Gastritis | 0 (0%) | 0 (0%) | 0 (0%) |
| Headache | 0 (0%) | 0 (0%) | 0 (0%) |
| Hematuria | 0 (0%) | 2 (12.5%) | 0 (0%) |
| Hemoglobin decreased | 0 (0%) | 0 (0%) | 0 (0%) |
| Hyperglycemia | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Adjuvant + AGS-V (N = 17) | AGS-V (N = 16) | Placebo (N = 16) |
|----------------------------|----------------------------------|-----------------------|-------------------------|
| Hypernatremia | 0 (0%) | 1 (6.25%) | 0 (0%) |
| Hypertension | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypocalcemia | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypoglycemia | 2 (11.76%) | 0 (0%) | 1 (6.25%) |
| Hypokalemia | 0 (0%) | 0 (0%) | 1 (6.25%) |
| Hyponatremia | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypophosphatemia | 0 (0%) | 0 (0%) | 0 (0%) |
| Influenza | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site erythema | 1 (5.88%) | 0 (0%) | 0 (0%) |
| Injection site induration | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site itching | 1 (5.88%) | 0 (0%) | 0 (0%) |
| Injection site pain | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site pruritus | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site swelling | 0 (0%) | 0 (0%) | 0 (0%) |
| Injury | 0 (0%) | 0 (0%) | 0 (0%) |
| Insect bite | 0 (0%) | 0 (0%) | 0 (0%) |
| Iron deficiency anemia | 0 (0%) | 0 (0%) | 0 (0%) |
| Knee pain | 0 (0%) | 0 (0%) | 0 (0%) |
| Laryngitis | 0 (0%) | 0 (0%) | 0 (0%) |
| Local swelling | 0 (0%) | 0 (0%) | 0 (0%) |
| Lymph node tenderness | 0 (0%) | 0 (0%) | 0 (0%) |
| Lymphocyte count increased | 0 (0%) | 0 (0%) | 0 (0%) |
| Muscle ache | 0 (0%) | 0 (0%) | 0 (0%) |
| Muscle strain | 0 (0%) | 0 (0%) | 0 (0%) |
| Myalgia | 0 (0%) | 0 (0%) | 0 (0%) |
| Nasal congestion | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Adjuvant + AGS-V (N = 17) | AGS-V (N = 16) | Placebo (N = 16) |
|-----------------------------------|----------------------------------|-----------------------|-------------------------|
| Nausea | 0 (0%) | 0 (0%) | 0 (0%) |
| Neutrophil count decreased | 0 (0%) | 0 (0%) | 0 (0%) |
| Oral pain | 0 (0%) | 0 (0%) | 0 (0%) |
| Peripheral neuropathy | 0 (0%) | 0 (0%) | 0 (0%) |
| Productive cough | 0 (0%) | 0 (0%) | 0 (0%) |
| Pruritic rash | 1 (5.88%) | 0 (0%) | 0 (0%) |
| Pruritus | 0 (0%) | 0 (0%) | 0 (0%) |
| Rash | 0 (0%) | 0 (0%) | 1 (6.25%) |
| Rhinorrhea | 0 (0%) | 0 (0%) | 0 (0%) |
| Sinusitis | 0 (0%) | 0 (0%) | 0 (0%) |
| Skin hyperpigmentation | 0 (0%) | 0 (0%) | 0 (0%) |
| Skin induration | 0 (0%) | 0 (0%) | 0 (0%) |
| Sore throat | 0 (0%) | 0 (0%) | 0 (0%) |
| Systolic hypertension | 0 (0%) | 0 (0%) | 0 (0%) |
| Tenderness | 0 (0%) | 0 (0%) | 0 (0%) |
| Tooth extraction | 0 (0%) | 0 (0%) | 0 (0%) |
| Torn bicep tendon | 1 (5.88%) | 0 (0%) | 0 (0%) |
| Upper respiratory tract infection | 0 (0%) | 0 (0%) | 0 (0%) |
| Urinary frequency | 0 (0%) | 0 (0%) | 0 (0%) |
| Urinary tract infection | 0 (0%) | 1 (6.25%) | 1 (6.25%) |
| Urine WBC increased | 0 (0%) | 0 (0%) | 0 (0%) |
| Urticaria | 1 (5.88%) | 0 (0%) | 0 (0%) |
| Vertigo | 0 (0%) | 0 (0%) | 1 (6.25%) |
| Vitamin D deficiency | 0 (0%) | 0 (0%) | 0 (0%) |
| Vomiting | 0 (0%) | 0 (0%) | 0 (0%) |
| WBC decreased | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Adjuvant + AGS-V (N = 17) | AGS-V (N = 16) | Placebo (N = 16) |
|---------------|----------------------------------|-----------------------|-------------------------|
| WBC increased | 0 (0%) | 0 (0%) | 0 (0%) |

Table 7 : Occurrence of Grade 4 Events by Treatment Group

| Event | Adjuvant + AGS-V (N = 17) | AGS-V (N = 16) | Placebo (N = 16) |
|--------------------------------------|----------------------------------|-----------------------|-------------------------|
| Abdominal cramps | 0 (0%) | 0 (0%) | 0 (0%) |
| Abdominal pain | 0 (0%) | 0 (0%) | 0 (0%) |
| Absolute neutrophil count, decreased | 0 (0%) | 0 (0%) | 0 (0%) |
| Acute sinusitis | 0 (0%) | 0 (0%) | 0 (0%) |
| ALT increased | 0 (0%) | 0 (0%) | 0 (0%) |
| Anxiety | 0 (0%) | 0 (0%) | 0 (0%) |
| Arthralgia | 0 (0%) | 0 (0%) | 0 (0%) |
| AST increased | 0 (0%) | 0 (0%) | 0 (0%) |
| Bilirubin total high | 0 (0%) | 0 (0%) | 0 (0%) |
| Blood eosinophils increased | 0 (0%) | 0 (0%) | 0 (0%) |
| Bradycardia | 0 (0%) | 0 (0%) | 0 (0%) |
| BUN increased | 0 (0%) | 0 (0%) | 0 (0%) |
| Campylobacter | 0 (0%) | 0 (0%) | 0 (0%) |
| Candida vaginitis | 0 (0%) | 0 (0%) | 0 (0%) |
| Chills | 0 (0%) | 0 (0%) | 0 (0%) |
| Common cold | 0 (0%) | 0 (0%) | 0 (0%) |
| Constipation | 0 (0%) | 0 (0%) | 0 (0%) |
| Coryza | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Adjuvant + AGS-V (N = 17) | AGS-V (N = 16) | Placebo (N = 16) |
|---------------------------|----------------------------------|-----------------------|-------------------------|
| CPK increased | 1 (5.88%) | 1 (6.25%) | 0 (0%) |
| Creatine kinase | 0 (0%) | 0 (0%) | 0 (0%) |
| Creatine kinase high | 0 (0%) | 0 (0%) | 0 (0%) |
| Creatinine increased | 0 (0%) | 0 (0%) | 0 (0%) |
| Dermatitis | 0 (0%) | 0 (0%) | 0 (0%) |
| Diaphoresis | 0 (0%) | 0 (0%) | 0 (0%) |
| Diarrhea | 0 (0%) | 0 (0%) | 0 (0%) |
| Difficulty sleeping | 0 (0%) | 0 (0%) | 0 (0%) |
| Dry cough | 0 (0%) | 0 (0%) | 0 (0%) |
| Eczema | 0 (0%) | 0 (0%) | 0 (0%) |
| Elevated liver enzymes | 0 (0%) | 0 (0%) | 0 (0%) |
| Elevated serum creatinine | 0 (0%) | 0 (0%) | 0 (0%) |
| Eosinophilia | 0 (0%) | 0 (0%) | 0 (0%) |
| Erythema | 0 (0%) | 0 (0%) | 0 (0%) |
| Eyelid Stye | 0 (0%) | 0 (0%) | 0 (0%) |
| Fatigue | 0 (0%) | 0 (0%) | 0 (0%) |
| Fever | 0 (0%) | 0 (0%) | 0 (0%) |
| Feverish | 0 (0%) | 0 (0%) | 0 (0%) |
| Gastritis | 0 (0%) | 0 (0%) | 0 (0%) |
| Headache | 0 (0%) | 0 (0%) | 0 (0%) |
| Hematuria | 0 (0%) | 0 (0%) | 0 (0%) |
| Hemoglobin decreased | 0 (0%) | 0 (0%) | 0 (0%) |
| Hyperglycemia | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypnatremia | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypertension | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypocalcemia | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Adjuvant + AGS-V (N = 17) | AGS-V (N = 16) | Placebo (N = 16) |
|----------------------------|----------------------------------|-----------------------|-------------------------|
| Hypoglycemia | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypokalemia | 0 (0%) | 0 (0%) | 0 (0%) |
| Hyponatremia | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypophosphatemia | 0 (0%) | 0 (0%) | 0 (0%) |
| Influenza | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site erythema | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site induration | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site itching | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site pain | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site pruritus | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site swelling | 0 (0%) | 0 (0%) | 0 (0%) |
| Injury | 0 (0%) | 0 (0%) | 0 (0%) |
| Insect bite | 0 (0%) | 0 (0%) | 0 (0%) |
| Iron deficiency anemia | 0 (0%) | 0 (0%) | 0 (0%) |
| Knee pain | 0 (0%) | 0 (0%) | 0 (0%) |
| Laryngitis | 0 (0%) | 0 (0%) | 0 (0%) |
| Local swelling | 0 (0%) | 0 (0%) | 0 (0%) |
| Lymph node tenderness | 0 (0%) | 0 (0%) | 0 (0%) |
| Lymphocyte count increased | 0 (0%) | 0 (0%) | 0 (0%) |
| Muscle ache | 0 (0%) | 0 (0%) | 0 (0%) |
| Muscle strain | 0 (0%) | 0 (0%) | 0 (0%) |
| Myalgia | 0 (0%) | 0 (0%) | 0 (0%) |
| Nasal congestion | 0 (0%) | 0 (0%) | 0 (0%) |
| Nausea | 0 (0%) | 0 (0%) | 0 (0%) |
| Neutrophil count decreased | 0 (0%) | 0 (0%) | 0 (0%) |
| Oral pain | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Adjuvant + AGS-V (N = 17) | AGS-V (N = 16) | Placebo (N = 16) |
|-----------------------------------|----------------------------------|-----------------------|-------------------------|
| Peripheral neuropathy | 0 (0%) | 0 (0%) | 0 (0%) |
| Productive cough | 0 (0%) | 0 (0%) | 0 (0%) |
| Pruritic rash | 0 (0%) | 0 (0%) | 0 (0%) |
| Pruritus | 0 (0%) | 0 (0%) | 0 (0%) |
| Rash | 0 (0%) | 0 (0%) | 0 (0%) |
| Rhinorrhea | 0 (0%) | 0 (0%) | 0 (0%) |
| Sinusitis | 0 (0%) | 0 (0%) | 0 (0%) |
| Skin hyperpigmentation | 0 (0%) | 0 (0%) | 0 (0%) |
| Skin induration | 0 (0%) | 0 (0%) | 0 (0%) |
| Sore throat | 0 (0%) | 0 (0%) | 0 (0%) |
| Systolic hypertension | 0 (0%) | 0 (0%) | 0 (0%) |
| Tenderness | 0 (0%) | 0 (0%) | 0 (0%) |
| Tooth extraction | 0 (0%) | 0 (0%) | 0 (0%) |
| Torn bicep tendon | 0 (0%) | 0 (0%) | 0 (0%) |
| Upper respiratory tract infection | 0 (0%) | 0 (0%) | 0 (0%) |
| Urinary frequency | 0 (0%) | 0 (0%) | 0 (0%) |
| Urinary tract infection | 0 (0%) | 0 (0%) | 0 (0%) |
| Urine WBC increased | 0 (0%) | 0 (0%) | 0 (0%) |
| Urticaria | 0 (0%) | 0 (0%) | 0 (0%) |
| Vertigo | 0 (0%) | 0 (0%) | 0 (0%) |
| Vitamin D deficiency | 0 (0%) | 0 (0%) | 0 (0%) |
| Vomiting | 0 (0%) | 0 (0%) | 0 (0%) |
| WBC decreased | 0 (0%) | 0 (0%) | 0 (0%) |
| WBC increased | 0 (0%) | 0 (0%) | 0 (0%) |

Table 8 : Occurrence of Max Grade Events Per Subject which are Unrelated to Treatment by Treatment Group

Note : In Tables 8-12, multiple occurrences of the same max grade event type with different relatedness are included in the respective table

| Event | AGS-V + Adjuvant (N = 17) | | | | | | AGS-V (N = 16) | | | | | | Placebo (N = 16) | | | | | |
|--------------------------------------|---------------------------|---------|------------|------------|-----------|-----------|----------------|---------|-----------|-----------|-----------|---------|------------------|---------|-----------|-----------|------------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Abdominal cramps | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Abdominal pain | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Absolute neutrophil count, decreased | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) |
| Acute sinusitis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| ALT increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Anxiety | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Arthralgia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| AST increased | 15 (88.24%) | 0 (0%) | 2 (11.76%) | 0 (0%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Bilirubin total high | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Blood eosinophils increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Bradycardia | 16 (94.12%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| BUN increased | 16 (94.12%) | 0 (0%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Campylobacter | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Candida vaginitis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Chills | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Common cold | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Constipation | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Coryza | 15 (88.24%) | 0 (0%) | 1 (5.88%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| CPK increased | 13 (76.47%) | 0 (0%) | 0 (0%) | 2 (11.76%) | 1 (5.88%) | 1 (5.88%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 10 (62.5%) | 0 (0%) | 1 (6.25%) | 2 (12.5%) | 3 (18.75%) | 0 (0%) |
| Creatine kinase | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | AGS-V + Adjuvant (N = 17) | | | | | | AGS-V (N = 16) | | | | | | Placebo (N = 16) | | | | | |
|---------------------------|---------------------------|---------|------------|-----------|---------|---------|----------------|---------|-----------|------------|-----------|---------|------------------|---------|-----------|-----------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Creatine kinase high | 16 (94.12%) | 0 (0%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Creatinine increased | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Dermatitis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Diaphoresis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Diarrhea | 16 (94.12%) | 0 (0%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Difficulty sleeping | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Dry cough | 15 (88.24%) | 0 (0%) | 2 (11.76%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Eczema | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Elevated liver enzymes | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Elevated serum creatinine | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Eosinophilia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Erythema | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Eyelid Stye | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Fatigue | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Fever | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Feverish | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Gastritis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Headache | 16 (94.12%) | 0 (0%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hematuria | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 13 (81.25%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hemoglobin decreased | 12 (70.59%) | 0 (0%) | 4 (23.53%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 11 (68.75%) | 0 (0%) | 2 (12.5%) | 3 (18.75%) | 0 (0%) | 0 (0%) | 13 (81.25%) | 0 (0%) | 2 (12.5%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| Hyperglycemia | 16 (94.12%) | 0 (0%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) |

| Event | AGS-V + Adjuvant (N = 17) | | | | | | AGS-V (N = 16) | | | | | | Placebo (N = 16) | | | | | |
|---------------------------|---------------------------|---------|------------|-----------|------------|---------|----------------|---------|-----------|------------|-----------|---------|------------------|---------|-----------|-----------|-----------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Hypnatremia | 14 (82.35%) | 0 (0%) | 2 (11.76%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 13 (81.25%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypertension | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypocalcemia | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypoglycemia | 14 (82.35%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 2 (11.76%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) | 13 (81.25%) | 0 (0%) | 1 (6.25%) | 1 (6.25%) | 1 (6.25%) | 0 (0%) |
| Hypokalemia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 1 (6.25%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 1 (6.25%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| Hyponatremia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypophosphatemia | 16 (94.12%) | 0 (0%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 12 (75%) | 0 (0%) | 1 (6.25%) | 3 (18.75%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| Influenza | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site erythema | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site induration | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site itching | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site pain | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site pruritus | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site swelling | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injury | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Insect bite | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Iron deficiency anemia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Knee pain | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Laryngitis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Local swelling | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Lymph node tenderness | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | AGS-V + Adjuvant (N = 17) | | | | | | AGS-V (N = 16) | | | | | | Placebo (N = 16) | | | | | |
|----------------------------|---------------------------|---------|-----------|-----------|---------|---------|----------------|---------|-----------|-----------|---------|---------|------------------|---------|-----------|---------|-----------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Lymphocyte count increased | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Muscle ache | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Muscle strain | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Myalgia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Nasal congestion | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Nausea | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Neutrophil count decreased | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 13 (81.25%) | 0 (0%) | 2 (12.5%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Oral pain | 16 (94.12%) | 0 (0%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Peripheral neuropathy | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Productive cough | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Pruritic rash | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Pruritus | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Rash | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) |
| Rhinorrhea | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Sinusitis | 16 (94.12%) | 0 (0%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Skin hyperpigmentation | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Skin induration | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Sore throat | 15 (88.24%) | 0 (0%) | 1 (5.88%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Systolic hypertension | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Tenderness | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Tooth extraction | 16 (94.12%) | 0 (0%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | AGS-V + Adjuvant (N = 17) | | | | | | AGS-V (N = 16) | | | | | | Placebo (N = 16) | | | | | |
|-----------------------------------|---------------------------|---------|--------------|---------|--------------|---------|----------------|---------|--------------|---------|--------------|---------|------------------|---------|--------------|--------------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Torn bicep tendon | 16 (94.12%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Upper respiratory tract infection | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urinary frequency | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urinary tract infection | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urine WBC increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urticaria | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Vertigo | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Vitamin D deficiency | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Vomiting | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| WBC decreased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| WBC increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |

Table 9 : Occurrence of Max Grade Events Per Subject which are Unlikely Related to Treatment by Treatment

| Event | Adjuvant + AGS-V (N = 17) | | | | | | AGS-V (N = 16) | | | | | | Placebo (N = 16) | | | | | |
|--------------------------------------|---------------------------|---------|--------------|---------|---------|---------|----------------|---------|--------------|---------|---------|---------|------------------|---------|--------------|---------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Abdominal cramps | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Abdominal pain | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Absolute neutrophil count, decreased | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Acute sinusitis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Adjuvant + AGS-V (N = 17) | | | | | | AGS-V (N = 16) | | | | | | Placebo (N = 16) | | | | | |
|-----------------------------|---------------------------|---------|-----------|-----------|-----------|---------|----------------|---------|---------|---------|---------|-----------|------------------|---------|-----------|-----------|-----------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| ALT increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Anxiety | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Arthralgia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| AST increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Bilirubin total high | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Blood eosinophils increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Bradycardia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| BUN increased | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Campylobacter | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Candida vaginitis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Chills | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Common cold | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Constipation | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Coryza | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| CPK increased | 16 (94.12%) | 0 (0%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| Creatine kinase | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| Creatine kinase high | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) |
| Creatinine increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Dermatitis | 16 (94.12%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Diaphoresis | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Diarrhea | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| | Adjuvant + AGS-V (N = 17) | | | | | | AGS-V (N = 16) | | | | | | Placebo (N = 16) | | | | | |
|---------------------------|---------------------------|---------|-------------|-----------|---------|---------|----------------|---------|-------------|-----------|-----------|---------|------------------|---------|-------------|-----------|-----------|---------|
| Event | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Difficulty sleeping | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Dry cough | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Eczema | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Elevated liver enzymes | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Elevated serum creatinine | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Eosinophilia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Erythema | 3 (17.65%) | 0 (0%) | 14 (82.35%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Eyelid Stye | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Fatigue | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Fever | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Feverish | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Gastritis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Headache | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hematuria | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) |
| Hemoglobin decreased | 14 (82.35%) | 0 (0%) | 3 (17.65%) | 0 (0%) | 0 (0%) | 0 (0%) | 13 (81.25%) | 0 (0%) | 2 (12.5%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hyperglycemia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypnatremia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| Hypertension | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypocalcemia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypoglycemia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypokalemia | 15 (88.24%) | 0 (0%) | 1 (5.88%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) |

| Event | Adjuvant + AGS-V (N = 17) | | | | | | AGS-V (N = 16) | | | | | | Placebo (N = 16) | | | | | |
|----------------------------|---------------------------|---------|----------------|--------------|---------|---------|----------------|---------|----------------|---------|---------|---------|------------------|---------|----------------|---------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Hyponatremia | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypophosphatemia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Influenza | 16 (94.12%) | 0 (0%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site erythema | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site induration | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site itching | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site pain | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site pruritus | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site swelling | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injury | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Insect bite | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Iron deficiency anemia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Knee pain | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Laryngitis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Local swelling | 1 (5.88%) | 0 (0%) | 16 (94.12%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Lymph node tenderness | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Lymphocyte count increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Muscle ache | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Muscle strain | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Myalgia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Nasal congestion | 15 (88.24%) | 0 (0%) | 2 (11.76%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Adjuvant + AGS-V (N = 17) | | | | | | AGS-V (N = 16) | | | | | | Placebo (N = 16) | | | | | |
|-----------------------------------|---------------------------|---------|-----------|-----------|-----------|---------|----------------|---------|-----------|-----------|---------|---------|------------------|---------|-----------|-----------|-----------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Nausea | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 13 (81.25%) | 0 (0%) | 2 (12.5%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Neutrophil count decreased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| Oral pain | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Peripheral neuropathy | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Productive cough | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Pruritic rash | 15 (88.24%) | 0 (0%) | 0 (0%) | 1 (5.88%) | 1 (5.88%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Pruritus | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Rash | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Rhinorrhea | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Sinusitis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Skin hyperpigmentation | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Skin induration | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Sore throat | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Systolic hypertension | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Tenderness | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Tooth extraction | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Torn bicep tendon | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Upper respiratory tract infection | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urinary frequency | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urinary tract infection | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) |
| Urine WBC increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Adjuvant + AGS-V (N = 17) | | | | | | AGS-V (N = 16) | | | | | | Placebo (N = 16) | | | | | |
|----------------------|---------------------------|---------|-----------|---------|---------|---------|----------------|---------|-----------|-----------|---------|---------|------------------|---------|---------|---------|-----------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Urticaria | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Vertigo | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) |
| Vitamin D deficiency | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Vomiting | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 1 (6.25%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| WBC decreased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| WBC increased | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

Table 10 : Occurrence of Max Grade Events Per Subject which are Possibly Related to Treatment by Treatment Group

| Event | Adjuvant + AGS-V (N = 17) | | | | | | AGS-V (N = 16) | | | | | | Placebo (N = 16) | | | | | |
|--------------------------------------|---------------------------|---------|------------|---------|---------|---------|----------------|---------|-----------|---------|---------|---------|------------------|---------|---------|---------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Abdominal cramps | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Abdominal pain | 15 (88.24%) | 0 (0%) | 2 (11.76%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Absolute neutrophil count, decreased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Acute sinusitis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| ALT increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Anxiety | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Arthralgia | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| AST increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Bilirubin total high | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Blood eosinophils increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Bradycardia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| | Adjuvant + AGS-V (N = 17) | | | | | | AGS-V (N = 16) | | | | | | Placebo (N = 16) | | | | | |
|---------------------------|---------------------------|---------|-----------|---------|---------|---------|----------------|---------|-----------|---------|---------|---------|------------------|---------|-----------|---------|---------|---------|
| Event | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| BUN increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Campylobacter | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Candida vaginitis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Chills | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Common cold | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Constipation | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Coryza | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| CPK increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Creatine kinase | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Creatine kinase high | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Creatinine increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Dermatitis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Diaphoresis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Diarrhea | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Difficulty sleeping | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Dry cough | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Eczema | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Elevated liver enzymes | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Elevated serum creatinine | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Eosinophilia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Erythema | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| | Adjuvant + AGS-V (N = 17) | | | | | | AGS-V (N = 16) | | | | | | Placebo (N = 16) | | | | | |
|---------------------------|---------------------------|---------|------------|-----------|---------|---------|----------------|---------|-----------|-----------|---------|---------|------------------|---------|-----------|---------|---------|---------|
| Event | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Eyelid Stye | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Fatigue | 15 (88.24%) | 0 (0%) | 2 (11.76%) | 0 (0%) | 0 (0%) | 0 (0%) | 12 (75%) | 0 (0%) | 4 (25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Fever | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Feverish | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Gastritis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Headache | 12 (70.59%) | 0 (0%) | 4 (23.53%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 12 (75%) | 0 (0%) | 2 (12.5%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hematuria | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hemoglobin decreased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hyperglycemia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hyponatremia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypertension | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypocalcemia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypoglycemia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypokalemia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hyponatremia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypophosphatemia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Influenza | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site erythema | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site induration | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site itching | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site pain | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Adjuvant + AGS-V (N = 17) | | | | | | AGS-V (N = 16) | | | | | | Placebo (N = 16) | | | | | |
|----------------------------|---------------------------|---------|------------|---------|---------|---------|----------------|---------|-----------|-----------|---------|---------|------------------|---------|-----------|---------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Injection site pruritus | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site swelling | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injury | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Insect bite | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Iron deficiency anemia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Knee pain | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Laryngitis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Local swelling | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Lymph node tenderness | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Lymphocyte count increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Muscle ache | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Muscle strain | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Myalgia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 1 (6.25%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Nasal congestion | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Nausea | 15 (88.24%) | 0 (0%) | 2 (11.76%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Neutrophil count decreased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Oral pain | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Peripheral neuropathy | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Productive cough | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Pruritic rash | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Pruritus | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| | Adjuvant + AGS-V (N = 17) | | | | | | AGS-V (N = 16) | | | | | | Placebo (N = 16) | | | | | |
|-----------------------------------|---------------------------|---------|---------|---------|-----------|---------|----------------|---------|-----------|---------|---------|---------|------------------|---------|-----------|---------|---------|---------|
| Event | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Rash | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Rhinorrhea | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Sinusitis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Skin hyperpigmentation | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Skin induration | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Sore throat | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Systolic hypertension | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Tenderness | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Tooth extraction | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Torn bicep tendon | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Upper respiratory tract infection | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urinary frequency | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urinary tract infection | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urine WBC increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urticaria | 16 (94.12%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Vertigo | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Vitamin D deficiency | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Vomiting | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| WBC decreased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| WBC increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

Table 11 : Occurrence of Max Grade Events Per Subject which are Probably Related to Treatment by Treatment Group

| Event | Adjuvant + AGS-V (N = 17) | | | | | | AGS-V (N = 16) | | | | | | Placebo (N = 16) | | | | | |
|--------------------------------------|---------------------------|---------|---------|---------------|---------|---------|----------------|---------|--------------|---------|---------|---------|------------------|---------|---------|---------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Abdominal cramps | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Abdominal pain | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Absolute neutrophil count, decreased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Acute sinusitis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| ALT increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Anxiety | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Arthralgia | 15 (88.24%) | 0 (0%) | 0 (0%) | 2 (11.76%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| AST increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Bilirubin total high | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Blood eosinophils increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Bradycardia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| BUN increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Campylobacter | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Candida vaginitis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Chills | 14 (82.35%) | 0 (0%) | 0 (0%) | 3 (17.65%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Common cold | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Adjuvant + AGS-V (N = 17) | | | | | | AGS-V (N = 16) | | | | | | Placebo (N = 16) | | | | | |
|---------------------------|---------------------------|---------|------------|------------|---------|---------|----------------|---------|-----------|---------|---------|---------|------------------|---------|-----------|-----------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Constipation | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Coryza | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| CPK increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Creatine kinase | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Creatine kinase high | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Creatinine increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Dermatitis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Diaphoresis | 16 (94.12%) | 0 (0%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Diarrhea | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Difficulty sleeping | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Dry cough | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Eczema | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Elevated liver enzymes | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Elevated serum creatinine | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Eosinophilia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Erythema | 16 (94.12%) | 0 (0%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Eyelid Styte | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Fatigue | 11 (64.71%) | 0 (0%) | 3 (17.65%) | 3 (17.65%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 1 (6.25%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| Fever | 16 (94.12%) | 0 (0%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Feverish | 12 (70.59%) | 0 (0%) | 2 (11.76%) | 3 (17.65%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Gastritis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Adjuvant + AGS-V (N = 17) | | | | | | AGS-V (N = 16) | | | | | | Placebo (N = 16) | | | | | |
|---------------------------|---------------------------|---------|---------------|---------------|---------|---------|----------------|---------|--------------|---------|---------|---------|------------------|---------|---------|---------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Headache | 13 (76.47%) | 0 (0%) | 2 (11.76%) | 2 (11.76%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hematuria | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hemoglobin decreased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hyperglycemia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypnatremia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypertension | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypocalcemia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypoglycemia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypokalemia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hyponatremia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypophosphatemia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Influenza | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site erythema | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site induration | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site itching | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site pain | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site pruritus | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site swelling | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injury | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Insect bite | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Iron deficiency anemia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Adjuvant + AGS-V (N = 17) | | | | | | AGS-V (N = 16) | | | | | | Placebo (N = 16) | | | | | |
|----------------------------|---------------------------|---------|------------|-----------|---------|---------|----------------|---------|-----------|---------|---------|---------|------------------|---------|-----------|-----------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Knee pain | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Laryngitis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Local swelling | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Lymph node tenderness | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Lymphocyte count increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Muscle ache | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Muscle strain | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Myalgia | 12 (70.59%) | 0 (0%) | 4 (23.53%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 1 (6.25%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| Nasal congestion | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Nausea | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Neutrophil count decreased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Oral pain | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Peripheral neuropathy | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Productive cough | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Pruritic rash | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Pruritus | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Rash | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Rhinorrhea | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Sinusitis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Skin hyperpigmentation | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Skin induration | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| | Adjuvant + AGS-V (N = 17) | | | | | | AGS-V (N = 16) | | | | | | Placebo (N = 16) | | | | | |
|-----------------------------------|----------------------------------|----------------|----------------|----------------|----------------|----------------|-----------------------|----------------|----------------|----------------|----------------|----------------|-------------------------|----------------|----------------|----------------|----------------|----------------|
| Event | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Sore throat | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Systolic hypertension | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Tenderness | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Tooth extraction | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Torn bicep tendon | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Upper respiratory tract infection | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urinary frequency | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urinary tract infection | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urine WBC increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urticaria | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Vertigo | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Vitamin D deficiency | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Vomiting | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| WBC decreased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| WBC increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

Table 12 : Occurrence of Max Grade Events Per Subject which are Definitely Related to Treatment by Treatment Group

| | Adjuvant + AGS-V (N = 17) | | | | | | AGS-V (N = 16) | | | | | | Placebo (N = 16) | | | | | |
|------------------|----------------------------------|----------------|----------------|----------------|----------------|----------------|-----------------------|----------------|----------------|----------------|----------------|----------------|-------------------------|----------------|----------------|----------------|----------------|----------------|
| Event | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Abdominal cramps | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Abdominal pain | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Adjuvant + AGS-V (N = 17) | | | | | | AGS-V (N = 16) | | | | | | Placebo (N = 16) | | | | | |
|--------------------------------------|---------------------------|---------|---------|---------|---------|---------|----------------|---------|---------|---------|---------|---------|------------------|---------|---------|---------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Absolute neutrophil count, decreased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Acute sinusitis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| ALT increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Anxiety | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Arthralgia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| AST increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Bilirubin total high | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Blood eosinophils increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Bradycardia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| BUN increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Campylobacter | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Candida vaginitis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Chills | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Common cold | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Constipation | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Coryza | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| CPK increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Creatine kinase | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Creatine kinase high | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Creatinine increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Adjuvant + AGS-V (N = 17) | | | | | | AGS-V (N = 16) | | | | | | Placebo (N = 16) | | | | | |
|---------------------------|---------------------------|---------|-----------|---------|---------|---------|----------------|---------|---------|---------|---------|---------|------------------|---------|---------|---------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Dermatitis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Diaphoresis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Diarrhea | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Difficulty sleeping | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Dry cough | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Eczema | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Elevated liver enzymes | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Elevated serum creatinine | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Eosinophilia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Erythema | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Eyelid Stye | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Fatigue | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Fever | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Feverish | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Gastritis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Headache | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hematuria | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hemoglobin decreased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hyperglycemia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypernatremia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypertension | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| | Adjuvant + AGS-V (N = 17) | | | | | | AGS-V (N = 16) | | | | | | Placebo (N = 16) | | | | | |
|----------------------------|---------------------------|-----------|------------|------------|-----------|---------|----------------|-----------|-----------|---------|---------|---------|------------------|-----------|------------|-----------|---------|---------|
| Event | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Hypocalcemia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypoglycemia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypokalemia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hyponatremia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypophosphatemia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Influenza | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site erythema | 9 (52.94%) | 1 (5.88%) | 3 (17.65%) | 3 (17.65%) | 1 (5.88%) | 0 (0%) | 13 (81.25%) | 2 (12.5%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 1 (6.25%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site induration | 15 (88.24%) | 1 (5.88%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site itching | 11 (64.71%) | 0 (0%) | 5 (29.41%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site pain | 8 (47.06%) | 0 (0%) | 7 (41.18%) | 2 (11.76%) | 0 (0%) | 0 (0%) | 10 (62.5%) | 0 (0%) | 6 (37.5%) | 0 (0%) | 0 (0%) | 0 (0%) | 12 (75%) | 0 (0%) | 3 (18.75%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| Injection site pruritus | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site swelling | 8 (47.06%) | 1 (5.88%) | 7 (41.18%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injury | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Insect bite | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Iron deficiency anemia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Knee pain | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Laryngitis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Local swelling | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Lymph node tenderness | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Lymphocyte count increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Muscle ache | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| | Adjuvant + AGS-V (N = 17) | | | | | | AGS-V (N = 16) | | | | | | Placebo (N = 16) | | | | | |
|-----------------------------------|---------------------------|---------|-----------|---------|---------|---------|----------------|---------|---------|---------|---------|---------|------------------|---------|---------|---------|---------|---------|
| Event | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Muscle strain | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Myalgia | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Nasal congestion | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Nausea | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Neutrophil count decreased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Oral pain | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Peripheral neuropathy | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Productive cough | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Pruritic rash | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Pruritus | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Rash | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Rhinorrhea | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Sinusitis | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Skin hyperpigmentation | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Skin induration | 16 (94.12%) | 0 (0%) | 1 (5.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Sore throat | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Systolic hypertension | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Tenderness | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Tooth extraction | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Torn bicep tendon | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Upper respiratory tract infection | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Adjuvant + AGS-V (N = 17) | | | | | | AGS-V (N = 16) | | | | | | Placebo (N = 16) | | | | | |
|-------------------------|---------------------------|---------|---------|---------|---------|---------|----------------|---------|---------|---------|---------|---------|------------------|---------|---------|---------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Urinary frequency | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urinary tract infection | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urine WBC increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urticaria | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Vertigo | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Vitamin D deficiency | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Vomiting | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| WBC decreased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| WBC increased | 17 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

Table 13 : Occurrence of “Worst” Relatedness to Treatment Per Subject by Treatment

| | Adjuvant + AGS-V (N = 17) | AGS-V (N =16) | Placebo (N = 16) |
|--------------------|---------------------------|---------------|------------------|
| Definitely Related | 16 (94.12%) | 6 (37.5%) | 4 (25%) |
| Probably Related | 1 (5.88%) | 0 (0%) | 2 (12.5%) |
| Possibly Related | 0 (0%) | 4 (25%) | 2 (12.5%) |
| Unlikely Related | 0 (0%) | 6 (37.5%) | 7 (43.75%) |
| Unrelated | 0 (0%) | 0 (0%) | 0 (0%) |
| No AEs | 0 (0%) | 0 (0%) | 1 (6.25%) |

Table 14 : Number of Subjects with Event Per Group and One-Sided Fisher’s Exact Test P-Values Comparing Vaccine to Placebo

| Event | Adjuvant + AGS-V (N = 17) | AGS-V (N = 16) | Placebo (N = 16) | Fisher's Exact P-value Adjuvant + AGS-V vs. Placebo | Fisher's Exact P-value AGS-V vs. Placebo |
|--------------------------------------|--------------------------------------|---------------------------|-----------------------------|--|---|
| Abdominal cramps | 0 | 1 | 0 | 1 | 0.5 |
| Abdominal pain | 3 | 2 | 1 | 0.32 | 0.5 |
| Absolute neutrophil count, decreased | 2 | 1 | 1 | 0.52 | 0.76 |
| Acute sinusitis | 0 | 0 | 1 | 1 | 1 |
| ALT increased | 0 | 3 | 0 | 1 | 0.11 |
| Anxiety | 0 | 1 | 0 | 1 | 0.5 |
| Arthralgia | 3 | 1 | 0 | 0.12 | 0.5 |
| AST increased | 2 | 2 | 1 | 0.52 | 0.5 |
| Bilirubin total high | 0 | 1 | 0 | 1 | 0.5 |
| Blood eosinophils increased | 0 | 1 | 0 | 1 | 0.5 |
| Bradycardia | 1 | 1 | 0 | 0.52 | 0.5 |
| BUN increased | 2 | 0 | 1 | 0.52 | 1 |
| Campylobacter | 0 | 0 | 1 | 1 | 1 |
| Candida vaginitis | 0 | 0 | 2 | 1 | 1 |
| Chills | 3 | 2 | 1 | 0.32 | 0.5 |
| Common cold | 1 | 0 | 1 | 0.77 | 1 |
| Constipation | 0 | 0 | 1 | 1 | 1 |
| Coryza | 2 | 0 | 1 | 0.52 | 1 |
| CPK increased | 5 | 2 | 6 | 0.81 | 0.98 |
| Creatine kinase | 0 | 0 | 1 | 1 | 1 |
| Creatine kinase high | 1 | 1 | 1 | 0.77 | 0.76 |
| Creatinine increased | 1 | 0 | 0 | 0.52 | 1 |
| Dermatitis | 1 | 0 | 0 | 0.52 | 1 |
| Diaphoresis | 2 | 2 | 1 | 0.52 | 0.5 |
| Diarrhea | 2 | 0 | 1 | 0.52 | 1 |
| Difficulty sleeping | 1 | 0 | 0 | 0.52 | 1 |

| Event | Adjuvant + AGS-V (N = 17) | AGS-V (N = 16) | Placebo (N = 16) | Fisher's Exact P-value Adjuvant + AGS-V vs. Placebo | Fisher's Exact P-value AGS-V vs. Placebo |
|---------------------------|--------------------------------------|---------------------------|-----------------------------|--|---|
| Dry cough | 2 | 0 | 0 | 0.26 | 1 |
| Eczema | 1 | 0 | 0 | 0.52 | 1 |
| Elevated liver enzymes | 1 | 0 | 0 | 0.52 | 1 |
| Elevated serum creatinine | 1 | 0 | 0 | 0.52 | 1 |
| Eosinophilia | 0 | 1 | 0 | 1 | 0.5 |
| Erythema | 15 | 15 | 15 | 0.88 | 0.76 |
| Eyelid Stye | 0 | 1 | 0 | 1 | 0.5 |
| Fatigue | 8 | 5 | 4 | 0.17 | 0.5 |
| Fever | 1 | 0 | 2 | 0.9 | 1 |
| Feverish | 7 | 1 | 3 | 0.15 | 0.95 |
| Gastritis | 0 | 0 | 1 | 1 | 1 |
| Headache | 8 | 7 | 4 | 0.17 | 0.23 |
| Hematuria | 1 | 3 | 3 | 0.96 | 0.67 |
| Hemoglobin decreased | 7 | 8 | 5 | 0.41 | 0.24 |
| Hyperglycemia | 1 | 2 | 2 | 0.9 | 0.7 |
| Hypernatremia | 3 | 4 | 3 | 0.7 | 0.5 |
| Hypertension | 1 | 0 | 0 | 0.52 | 1 |
| Hypocalcemia | 1 | 1 | 0 | 0.52 | 0.5 |
| Hypoglycemia | 3 | 2 | 3 | 0.7 | 0.83 |
| Hypokalemia | 2 | 2 | 3 | 0.85 | 0.83 |
| Hyponatremia | 1 | 0 | 0 | 0.52 | 1 |
| Hypophosphatemia | 1 | 4 | 2 | 0.9 | 0.33 |
| Influenza | 1 | 0 | 0 | 0.52 | 1 |
| Injection site erythema | 8 | 3 | 2 | 0.04* | 0.5 |
| Injection site induration | 2 | 0 | 0 | 0.26 | 1 |
| Injection site itching | 7 | 1 | 0 | 0.005* | 0.5 |

| Event | Adjuvant + AGS-V (N = 17) | AGS-V (N = 16) | Placebo (N = 16) | Fisher's Exact P-value Adjuvant + AGS-V vs. Placebo | Fisher's Exact P-value AGS-V vs. Placebo |
|----------------------------|--------------------------------------|---------------------------|-----------------------------|--|---|
| Injection site pain | 9 | 6 | 4 | 0.099* | 0.35 |
| Injection site pruritus | 0 | 2 | 0 | 1 | 0.24 |
| Injection site swelling | 9 | 2 | 1 | 0.004* | 0.5 |
| Injury | 0 | 1 | 0 | 1 | 0.5 |
| Insect bite | 0 | 0 | 1 | 1 | 1 |
| Iron deficiency anemia | 0 | 1 | 0 | 1 | 0.5 |
| Knee pain | 1 | 0 | 0 | 0.52 | 1 |
| Laryngitis | 0 | 0 | 1 | 1 | 1 |
| Local swelling | 16 | 15 | 15 | 0.74 | 0.76 |
| Lymph node tenderness | 1 | 0 | 0 | 0.52 | 1 |
| Lymphocyte count increased | 1 | 0 | 0 | 0.52 | 1 |
| Muscle ache | 2 | 0 | 0 | 0.26 | 1 |
| Muscle strain | 1 | 0 | 0 | 0.52 | 1 |
| Myalgia | 5 | 3 | 5 | 0.69 | 0.89 |
| Nasal congestion | 2 | 1 | 1 | 0.52 | 0.76 |
| Nausea | 2 | 3 | 2 | 0.72 | 0.5 |
| Neutrophil count decreased | 1 | 4 | 3 | 0.96 | 0.5 |
| Oral pain | 1 | 0 | 0 | 0.52 | 1 |
| Peripheral neuropathy | 0 | 0 | 1 | 1 | 1 |
| Productive cough | 1 | 0 | 0 | 0.52 | 1 |
| Pruritic rash | 2 | 1 | 0 | 0.26 | 0.5 |
| Pruritus | 1 | 0 | 0 | 0.52 | 1 |
| Rash | 0 | 0 | 3 | 1 | 1 |
| Rhinorrhea | 1 | 0 | 1 | 0.77 | 1 |
| Sinusitis | 1 | 0 | 0 | 0.52 | 1 |
| Skin hyperpigmentation | 1 | 1 | 0 | 0.52 | 0.5 |

| Event | Adjuvant + AGS-V (N = 17) | AGS-V (N = 16) | Placebo (N = 16) | Fisher's Exact P-value Adjuvant + AGS-V vs. Placebo | Fisher's Exact P-value AGS-V vs. Placebo |
|-----------------------------------|--------------------------------------|---------------------------|-----------------------------|--|---|
| Skin induration | 1 | 0 | 0 | 0.52 | 1 |
| Sore throat | 2 | 1 | 1 | 0.52 | 0.76 |
| Systolic hypertension | 0 | 1 | 0 | 1 | 0.5 |
| Tenderness | 1 | 0 | 0 | 0.52 | 1 |
| Tooth extraction | 1 | 0 | 0 | 0.52 | 1 |
| Torn bicep tendon | 1 | 0 | 0 | 0.52 | 1 |
| Upper respiratory tract infection | 0 | 1 | 0 | 1 | 0.5 |
| Urinary frequency | 0 | 0 | 1 | 1 | 1 |
| Urinary tract infection | 0 | 1 | 1 | 1 | 0.76 |
| Urine WBC increased | 0 | 2 | 0 | 1 | 0.24 |
| Urticaria | 1 | 0 | 0 | 0.52 | 1 |
| Vertigo | 0 | 0 | 1 | 1 | 1 |
| Vitamin D deficiency | 1 | 0 | 0 | 0.52 | 1 |
| Vomiting | 0 | 2 | 0 | 1 | 0.24 |
| WBC decreased | 0 | 0 | 2 | 1 | 1 |
| WBC increased | 1 | 2 | 1 | 0.77 | 0.5 |

* Indicates one-sided Fisher's Exact p-value < 0.1

Supplemental Table 3. Adverse Events Summary (combining vaccine and adjuvanted vaccine groups)

Table 1 : Summary of Max Grade Adverse Events Per Subject

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|--------------------------------------|------------------|---------|---------------|--------------|--------------|---------|------------------|---------|--------------|---------|--------------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Abdominal cramps | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Abdominal pain | 28 (84.85%) | 0 (0%) | 5 (15.15%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Absolute neutrophil count, decreased | 30 (90.91%) | 0 (0%) | 2 (6.06%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) |
| Acute sinusitis | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| ALT increased | 30 (90.91%) | 0 (0%) | 3 (9.09%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Anxiety | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Arthralgia | 29 (87.88%) | 0 (0%) | 2 (6.06%) | 2 (6.06%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| AST increased | 29 (87.88%) | 0 (0%) | 4 (12.12%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Bilirubin total high | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Blood eosinophils increased | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Bradycardia | 31 (93.94%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| BUN increased | 31 (93.94%) | 0 (0%) | 1 (3.03%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Campylobacter | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Candida vaginitis | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Chills | 28 (84.85%) | 0 (0%) | 2 (6.06%) | 3 (9.09%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|---------------------------|------------------|---------|----------------|---------------|--------------|--------------|------------------|---------|----------------|--------------|---------------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Common cold | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Constipation | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Coryza | 31 (93.94%) | 0 (0%) | 1 (3.03%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| CPK increased | 26 (78.79%) | 0 (0%) | 0 (0%) | 4 (12.12%) | 1 (3.03%) | 2 (6.06%) | 10 (62.5%) | 0 (0%) | 1 (6.25%) | 2 (12.5%) | 3 (18.75%) | 0 (0%) |
| Creatine kinase | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| Creatine kinase high | 31 (93.94%) | 0 (0%) | 0 (0%) | 2 (6.06%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) |
| Creatinine increased | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Dermatitis | 32 (96.97%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Diaphoresis | 29 (87.88%) | 0 (0%) | 3 (9.09%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Diarrhea | 31 (93.94%) | 0 (0%) | 1 (3.03%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Difficulty sleeping | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Dry cough | 31 (93.94%) | 0 (0%) | 2 (6.06%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Eczema | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Elevated liver enzymes | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Elevated serum creatinine | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Eosinophilia | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Erythema | 3 (9.09%) | 0 (0%) | 29 (87.88%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|----------------------|------------------|---------|---------------|---------------|--------------|---------|------------------|---------|---------------|--------------|--------------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Eyelid Styte | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Fatigue | 20 (60.61%) | 0 (0%) | 10 (30.3%) | 3 (9.09%) | 0 (0%) | 0 (0%) | 12 (75%) | 0 (0%) | 3 (18.75%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| Fever | 32 (96.97%) | 0 (0%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Feverish | 25 (75.76%) | 0 (0%) | 5 (15.15%) | 3 (9.09%) | 0 (0%) | 0 (0%) | 13 (81.25%) | 0 (0%) | 3 (18.75%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Gastritis | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Headache | 18 (54.55%) | 0 (0%) | 9 (27.27%) | 6 (18.18%) | 0 (0%) | 0 (0%) | 12 (75%) | 0 (0%) | 4 (25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hematuria | 29 (87.88%) | 0 (0%) | 2 (6.06%) | 0 (0%) | 2 (6.06%) | 0 (0%) | 13 (81.25%) | 0 (0%) | 1 (6.25%) | 2 (12.5%) | 0 (0%) | 0 (0%) |
| Hemoglobin decreased | 18 (54.55%) | 0 (0%) | 10 (30.3%) | 5 (15.15%) | 0 (0%) | 0 (0%) | 11 (68.75%) | 0 (0%) | 4 (25%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| Hyperglycemia | 30 (90.91%) | 0 (0%) | 0 (0%) | 3 (9.09%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) |
| Hypernatremia | 26 (78.79%) | 0 (0%) | 5 (15.15%) | 1 (3.03%) | 1 (3.03%) | 0 (0%) | 13 (81.25%) | 0 (0%) | 2 (12.5%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| Hypertension | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypocalcemia | 31 (93.94%) | 0 (0%) | 2 (6.06%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypoglycemia | 28 (84.85%) | 0 (0%) | 3 (9.09%) | 0 (0%) | 2 (6.06%) | 0 (0%) | 13 (81.25%) | 0 (0%) | 1 (6.25%) | 1 (6.25%) | 1 (6.25%) | 0 (0%) |
| Hypokalemia | 29 (87.88%) | 0 (0%) | 2 (6.06%) | 2 (6.06%) | 0 (0%) | 0 (0%) | 13 (81.25%) | 0 (0%) | 1 (6.25%) | 1 (6.25%) | 1 (6.25%) | 0 (0%) |
| Hyponatremia | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypophosphatemia | 28 (84.85%) | 0 (0%) | 1 (3.03%) | 4 (12.12%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 1 (6.25%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| Influenza | 32 (96.97%) | 0 (0%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|----------------------------|------------------|--------------|----------------|--------------|--------------|---------|------------------|--------------|----------------|--------------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Injection site erythema | 22 (66.67%) | 3 (9.09%) | 4 (12.12%) | 3 (9.09%) | 1 (3.03%) | 0 (0%) | 14 (87.5%) | 1 (6.25%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site induration | 31 (93.94%) | 1 (3.03%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site itching | 25 (75.76%) | 0 (0%) | 7 (21.21%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site pain | 18 (54.55%) | 0 (0%) | 13 (39.39%) | 2 (6.06%) | 0 (0%) | 0 (0%) | 12 (75%) | 0 (0%) | 3 (18.75%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| Injection site pruritus | 31 (93.94%) | 0 (0%) | 2 (6.06%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site swelling | 22 (66.67%) | 3 (9.09%) | 7 (21.21%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injury | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Insect bite | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Iron deficiency anemia | 32 (96.97%) | 0 (0%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Knee pain | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Laryngitis | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Local swelling | 2 (6.06%) | 0 (0%) | 31 (93.94%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Lymph node tenderness | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Lymphocyte count increased | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Muscle ache | 31 (93.94%) | 0 (0%) | 2 (6.06%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Muscle strain | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Myalgia | 25 (75.76%) | 0 (0%) | 6 (18.18%) | 2 (6.06%) | 0 (0%) | 0 (0%) | 11 (68.75%) | 0 (0%) | 4 (25%) | 1 (6.25%) | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|----------------------------|------------------|---------|---------------|--------------|--------------|---------|------------------|---------|--------------|--------------|--------------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Nasal congestion | 30 (90.91%) | 0 (0%) | 3 (9.09%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Nausea | 28 (84.85%) | 0 (0%) | 4 (12.12%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Neutrophil count decreased | 28 (84.85%) | 0 (0%) | 4 (12.12%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 13 (81.25%) | 0 (0%) | 2 (12.5%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| Oral pain | 32 (96.97%) | 0 (0%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Peripheral neuropathy | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Productive cough | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Pruritic rash | 30 (90.91%) | 0 (0%) | 1 (3.03%) | 1 (3.03%) | 1 (3.03%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Pruritus | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Rash | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 13 (81.25%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 1 (6.25%) | 0 (0%) |
| Rhinorrhea | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Sinusitis | 32 (96.97%) | 0 (0%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Skin hyperpigmentation | 31 (93.94%) | 0 (0%) | 2 (6.06%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Skin induration | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Sore throat | 30 (90.91%) | 0 (0%) | 1 (3.03%) | 2 (6.06%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Systolic hypertension | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Tenderness | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Tooth extraction | 32 (96.97%) | 0 (0%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|-----------------------------------|------------------|---------|--------------|--------------|--------------|---------|------------------|---------|--------------|--------------|--------------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Torn bicep tendon | 32 (96.97%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Upper respiratory tract infection | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urinary frequency | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urinary tract infection | 32 (96.97%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) |
| Urine WBC increased | 31 (93.94%) | 0 (0%) | 2 (6.06%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urticaria | 32 (96.97%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Vertigo | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) |
| Vitamin D deficiency | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Vomiting | 31 (93.94%) | 0 (0%) | 1 (3.03%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| WBC decreased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 1 (6.25%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| WBC increased | 30 (90.91%) | 0 (0%) | 3 (9.09%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |

Table 2 : Counts of Adverse Events by Treatment Group

| | Vaccine (N = 33) | Placebo (N = 16) |
|--|---------------------|--------------------|
| Number of Subjects with one or more AE (percent) | 33 (100%) | 15 (93.8%) |
| Mean Number of AEs (SD, SE) | 13.15 (7.86 , 1.37) | 9.81 (6.25 , 1.56) |
| Median Number of AEs (IQR) | 11 (12) | 10 (9.5) |
| Min, Max Number of AEs | 2, 33 | 0, 22 |
| Number of Subjects with one or more AE Grade 3 or Higher (percent) | 13 (39%) | 7 (44%) |
| Mean Number of AEs Grade 3 or Higher | 0.55 (0.79 , 0.14) | 0.63 (0.89, 0.22) |

Table 3 : Occurrence of Grade 0 Events by Treatment Group**Note : In Tables 3-7, multiple occurrences of the same event type with different grades are included in the respective table**

| Event | Vaccine (N = 33) | Placebo (N = 16) |
|--------------------------------------|-------------------------|-------------------------|
| Abdominal cramps | 0 (0%) | 0 (0%) |
| Abdominal pain | 0 (0%) | 0 (0%) |
| Absolute neutrophil count, decreased | 0 (0%) | 0 (0%) |
| Acute sinusitis | 0 (0%) | 0 (0%) |
| ALT increased | 0 (0%) | 0 (0%) |
| Anxiety | 0 (0%) | 0 (0%) |
| Arthralgia | 0 (0%) | 0 (0%) |
| AST increased | 0 (0%) | 0 (0%) |
| Bilirubin total high | 0 (0%) | 0 (0%) |
| Blood eosinophils increased | 0 (0%) | 0 (0%) |
| Bradycardia | 0 (0%) | 0 (0%) |
| BUN increased | 0 (0%) | 0 (0%) |
| Campylobacter | 0 (0%) | 0 (0%) |
| Candida vaginitis | 0 (0%) | 0 (0%) |
| Chills | 0 (0%) | 0 (0%) |
| Common cold | 0 (0%) | 0 (0%) |
| Constipation | 0 (0%) | 0 (0%) |
| Coryza | 0 (0%) | 0 (0%) |
| CPK increased | 0 (0%) | 0 (0%) |
| Creatine kinase | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | Placebo (N = 16) |
|---------------------------|-------------------------|-------------------------|
| Creatine kinase high | 0 (0%) | 0 (0%) |
| Creatinine increased | 0 (0%) | 0 (0%) |
| Dermatitis | 0 (0%) | 0 (0%) |
| Diaphoresis | 0 (0%) | 0 (0%) |
| Diarrhea | 0 (0%) | 0 (0%) |
| Difficulty sleeping | 0 (0%) | 0 (0%) |
| Dry cough | 0 (0%) | 0 (0%) |
| Eczema | 0 (0%) | 0 (0%) |
| Elevated liver enzymes | 0 (0%) | 0 (0%) |
| Elevated serum creatinine | 0 (0%) | 0 (0%) |
| Eosinophilia | 0 (0%) | 0 (0%) |
| Erythema | 0 (0%) | 0 (0%) |
| Eyelid Stye | 0 (0%) | 0 (0%) |
| Fatigue | 0 (0%) | 0 (0%) |
| Fever | 0 (0%) | 0 (0%) |
| Feverish | 0 (0%) | 0 (0%) |
| Gastritis | 0 (0%) | 0 (0%) |
| Headache | 0 (0%) | 0 (0%) |
| Hematuria | 0 (0%) | 0 (0%) |
| Hemoglobin decreased | 0 (0%) | 0 (0%) |
| Hyperglycemia | 0 (0%) | 0 (0%) |
| Hypernatremia | 0 (0%) | 0 (0%) |
| Hypertension | 0 (0%) | 0 (0%) |
| Hypocalcemia | 0 (0%) | 0 (0%) |
| Hypoglycemia | 0 (0%) | 0 (0%) |
| Hypokalemia | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | Placebo (N = 16) |
|----------------------------|-------------------------|-------------------------|
| Hyponatremia | 0 (0%) | 0 (0%) |
| Hypophosphatemia | 0 (0%) | 0 (0%) |
| Influenza | 0 (0%) | 0 (0%) |
| Injection site erythema | 6 (18.18%) | 1 (6.25%) |
| Injection site induration | 1 (3.03%) | 0 (0%) |
| Injection site itching | 0 (0%) | 0 (0%) |
| Injection site pain | 0 (0%) | 0 (0%) |
| Injection site pruritus | 0 (0%) | 0 (0%) |
| Injection site swelling | 4 (12.12%) | 1 (6.25%) |
| Injury | 0 (0%) | 0 (0%) |
| Insect bite | 0 (0%) | 0 (0%) |
| Iron deficiency anemia | 0 (0%) | 0 (0%) |
| Knee pain | 0 (0%) | 0 (0%) |
| Laryngitis | 0 (0%) | 0 (0%) |
| Local swelling | 0 (0%) | 0 (0%) |
| Lymph node tenderness | 0 (0%) | 0 (0%) |
| Lymphocyte count increased | 0 (0%) | 0 (0%) |
| Muscle ache | 0 (0%) | 0 (0%) |
| Muscle strain | 0 (0%) | 0 (0%) |
| Myalgia | 0 (0%) | 0 (0%) |
| Nasal congestion | 0 (0%) | 0 (0%) |
| Nausea | 0 (0%) | 0 (0%) |
| Neutrophil count decreased | 0 (0%) | 0 (0%) |
| Oral pain | 0 (0%) | 0 (0%) |
| Peripheral neuropathy | 0 (0%) | 0 (0%) |
| Productive cough | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | Placebo (N = 16) |
|-----------------------------------|-------------------------|-------------------------|
| Pruritic rash | 0 (0%) | 0 (0%) |
| Pruritus | 0 (0%) | 0 (0%) |
| Rash | 0 (0%) | 0 (0%) |
| Rhinorrhea | 0 (0%) | 0 (0%) |
| Sinusitis | 0 (0%) | 0 (0%) |
| Skin hyperpigmentation | 0 (0%) | 0 (0%) |
| Skin induration | 0 (0%) | 0 (0%) |
| Sore throat | 0 (0%) | 0 (0%) |
| Systolic hypertension | 0 (0%) | 0 (0%) |
| Tenderness | 0 (0%) | 0 (0%) |
| Tooth extraction | 0 (0%) | 0 (0%) |
| Torn bicep tendon | 0 (0%) | 0 (0%) |
| Upper respiratory tract infection | 0 (0%) | 0 (0%) |
| Urinary frequency | 0 (0%) | 0 (0%) |
| Urinary tract infection | 0 (0%) | 0 (0%) |
| Urine WBC increased | 0 (0%) | 0 (0%) |
| Urticaria | 0 (0%) | 0 (0%) |
| Vertigo | 0 (0%) | 0 (0%) |
| Vitamin D deficiency | 0 (0%) | 0 (0%) |
| Vomiting | 0 (0%) | 0 (0%) |
| WBC decreased | 0 (0%) | 0 (0%) |
| WBC increased | 0 (0%) | 0 (0%) |

Table 4 : Occurrence of Grade 1 Events by Treatment Group

| Event | Vaccine (N = 33) | Placebo (N = 16) |
|------------------|-------------------------|-------------------------|
| Abdominal cramps | 1 (3.03%) | 0 (0%) |
| Abdominal pain | 5 (15.15%) | 1 (6.25%) |

| Event | Vaccine (N = 33) | Placebo (N = 16) |
|--------------------------------------|-------------------------|-------------------------|
| Absolute neutrophil count, decreased | 3 (9.09%) | 1 (6.25%) |
| Acute sinusitis | 0 (0%) | 1 (6.25%) |
| ALT increased | 3 (9.09%) | 0 (0%) |
| Anxiety | 1 (3.03%) | 0 (0%) |
| Arthralgia | 3 (9.09%) | 0 (0%) |
| AST increased | 4 (12.12%) | 1 (6.25%) |
| Bilirubin total high | 1 (3.03%) | 0 (0%) |
| Blood eosinophils increased | 1 (3.03%) | 0 (0%) |
| Bradycardia | 2 (6.06%) | 0 (0%) |
| BUN increased | 2 (6.06%) | 1 (6.25%) |
| Campylobacter | 0 (0%) | 1 (6.25%) |
| Candida vaginitis | 0 (0%) | 2 (12.5%) |
| Chills | 3 (9.09%) | 1 (6.25%) |
| Common cold | 1 (3.03%) | 1 (6.25%) |
| Constipation | 0 (0%) | 1 (6.25%) |
| Coryza | 1 (3.03%) | 1 (6.25%) |
| CPK increased | 2 (6.06%) | 4 (25%) |
| Creatine kinase | 0 (0%) | 0 (0%) |
| Creatine kinase high | 1 (3.03%) | 0 (0%) |
| Creatinine increased | 1 (3.03%) | 0 (0%) |
| Dermatitis | 0 (0%) | 0 (0%) |
| Diaphoresis | 3 (9.09%) | 1 (6.25%) |
| Diarrhea | 1 (3.03%) | 1 (6.25%) |
| Difficulty sleeping | 1 (3.03%) | 0 (0%) |
| Dry cough | 2 (6.06%) | 0 (0%) |
| Eczema | 1 (3.03%) | 0 (0%) |

| Event | Vaccine (N = 33) | Placebo (N = 16) |
|---------------------------|-------------------------|-------------------------|
| Elevated liver enzymes | 1 (3.03%) | 0 (0%) |
| Elevated serum creatinine | 1 (3.03%) | 0 (0%) |
| Eosinophilia | 1 (3.03%) | 0 (0%) |
| Erythema | 30 (90.91%) | 15 (93.75%) |
| Eyelid Stye | 1 (3.03%) | 0 (0%) |
| Fatigue | 13 (39.39%) | 4 (25%) |
| Fever | 0 (0%) | 2 (12.5%) |
| Feverish | 6 (18.18%) | 3 (18.75%) |
| Gastritis | 0 (0%) | 1 (6.25%) |
| Headache | 13 (39.39%) | 4 (25%) |
| Hematuria | 2 (6.06%) | 2 (12.5%) |
| Hemoglobin decreased | 15 (45.45%) | 5 (31.25%) |
| Hyperglycemia | 2 (6.06%) | 1 (6.25%) |
| Hypernatremia | 6 (18.18%) | 2 (12.5%) |
| Hypertension | 1 (3.03%) | 0 (0%) |
| Hypocalcemia | 2 (6.06%) | 0 (0%) |
| Hypoglycemia | 4 (12.12%) | 2 (12.5%) |
| Hypokalemia | 2 (6.06%) | 1 (6.25%) |
| Hyponatremia | 1 (3.03%) | 0 (0%) |
| Hypophosphatemia | 3 (9.09%) | 2 (12.5%) |
| Influenza | 0 (0%) | 0 (0%) |
| Injection site erythema | 6 (18.18%) | 1 (6.25%) |
| Injection site induration | 1 (3.03%) | 0 (0%) |
| Injection site itching | 7 (21.21%) | 0 (0%) |
| Injection site pain | 15 (45.45%) | 4 (25%) |
| Injection site pruritus | 2 (6.06%) | 0 (0%) |

| Event | Vaccine (N = 33) | Placebo (N = 16) |
|----------------------------|-------------------------|-------------------------|
| Injection site swelling | 8 (24.24%) | 0 (0%) |
| Injury | 1 (3.03%) | 0 (0%) |
| Insect bite | 0 (0%) | 1 (6.25%) |
| Iron deficiency anemia | 0 (0%) | 0 (0%) |
| Knee pain | 1 (3.03%) | 0 (0%) |
| Laryngitis | 0 (0%) | 1 (6.25%) |
| Local swelling | 31 (93.94%) | 15 (93.75%) |
| Lymph node tenderness | 1 (3.03%) | 0 (0%) |
| Lymphocyte count increased | 1 (3.03%) | 0 (0%) |
| Muscle ache | 2 (6.06%) | 0 (0%) |
| Muscle strain | 1 (3.03%) | 0 (0%) |
| Myalgia | 8 (24.24%) | 5 (31.25%) |
| Nasal congestion | 3 (9.09%) | 1 (6.25%) |
| Nausea | 5 (15.15%) | 2 (12.5%) |
| Neutrophil count decreased | 5 (15.15%) | 2 (12.5%) |
| Oral pain | 0 (0%) | 0 (0%) |
| Peripheral neuropathy | 0 (0%) | 1 (6.25%) |
| Productive cough | 1 (3.03%) | 0 (0%) |
| Pruritic rash | 1 (3.03%) | 0 (0%) |
| Pruritus | 1 (3.03%) | 0 (0%) |
| Rash | 0 (0%) | 2 (12.5%) |
| Rhinorrhea | 1 (3.03%) | 1 (6.25%) |
| Sinusitis | 0 (0%) | 0 (0%) |
| Skin hyperpigmentation | 2 (6.06%) | 0 (0%) |
| Skin induration | 1 (3.03%) | 0 (0%) |
| Sore throat | 3 (9.09%) | 1 (6.25%) |

| Event | Vaccine (N = 33) | Placebo (N = 16) |
|-----------------------------------|-------------------------|-------------------------|
| Systolic hypertension | 1 (3.03%) | 0 (0%) |
| Tenderness | 1 (3.03%) | 0 (0%) |
| Tooth extraction | 0 (0%) | 0 (0%) |
| Torn bicep tendon | 0 (0%) | 0 (0%) |
| Upper respiratory tract infection | 1 (3.03%) | 0 (0%) |
| Urinary frequency | 0 (0%) | 1 (6.25%) |
| Urinary tract infection | 0 (0%) | 0 (0%) |
| Urine WBC increased | 2 (6.06%) | 0 (0%) |
| Urticaria | 0 (0%) | 0 (0%) |
| Vertigo | 0 (0%) | 0 (0%) |
| Vitamin D deficiency | 1 (3.03%) | 0 (0%) |
| Vomiting | 1 (3.03%) | 0 (0%) |
| WBC decreased | 0 (0%) | 2 (12.5%) |
| WBC increased | 3 (9.09%) | 1 (6.25%) |

Table 5 : Occurrence of Grade 2 Events by Treatment Group

| Event | Vaccine (N = 33) | Placebo (N = 16) |
|--------------------------------------|-------------------------|-------------------------|
| Abdominal cramps | 0 (0%) | 0 (0%) |
| Abdominal pain | 0 (0%) | 0 (0%) |
| Absolute neutrophil count, decreased | 1 (3.03%) | 1 (6.25%) |
| Acute sinusitis | 0 (0%) | 0 (0%) |
| ALT increased | 0 (0%) | 0 (0%) |
| Anxiety | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | Placebo (N = 16) |
|-----------------------------|-------------------------|-------------------------|
| Arthralgia | 2 (6.06%) | 0 (0%) |
| AST increased | 0 (0%) | 0 (0%) |
| Bilirubin total high | 0 (0%) | 0 (0%) |
| Blood eosinophils increased | 0 (0%) | 0 (0%) |
| Bradycardia | 0 (0%) | 0 (0%) |
| BUN increased | 1 (3.03%) | 0 (0%) |
| Campylobacter | 0 (0%) | 0 (0%) |
| Candida vaginitis | 0 (0%) | 0 (0%) |
| Chills | 3 (9.09%) | 0 (0%) |
| Common cold | 0 (0%) | 0 (0%) |
| Constipation | 0 (0%) | 0 (0%) |
| Coryza | 1 (3.03%) | 0 (0%) |
| CPK increased | 7 (21.21%) | 4 (25%) |
| Creatine kinase | 0 (0%) | 1 (6.25%) |
| Creatine kinase high | 2 (6.06%) | 0 (0%) |
| Creatinine increased | 0 (0%) | 0 (0%) |
| Dermatitis | 0 (0%) | 0 (0%) |
| Diaphoresis | 1 (3.03%) | 0 (0%) |
| Diarrhea | 1 (3.03%) | 0 (0%) |
| Difficulty sleeping | 0 (0%) | 0 (0%) |
| Dry cough | 0 (0%) | 0 (0%) |
| Eczema | 0 (0%) | 0 (0%) |
| Elevated liver enzymes | 0 (0%) | 0 (0%) |
| Elevated serum creatinine | 0 (0%) | 0 (0%) |
| Eosinophilia | 0 (0%) | 0 (0%) |
| Erythema | 1 (3.03%) | 0 (0%) |

| Event | Vaccine (N = 33) | Placebo (N = 16) |
|---------------------------|-------------------------|-------------------------|
| Eyelid Stye | 0 (0%) | 0 (0%) |
| Fatigue | 3 (9.09%) | 1 (6.25%) |
| Fever | 1 (3.03%) | 0 (0%) |
| Feverish | 3 (9.09%) | 0 (0%) |
| Gastritis | 0 (0%) | 0 (0%) |
| Headache | 6 (18.18%) | 0 (0%) |
| Hematuria | 0 (0%) | 2 (12.5%) |
| Hemoglobin decreased | 5 (15.15%) | 1 (6.25%) |
| Hyperglycemia | 3 (9.09%) | 2 (12.5%) |
| Hypernatremia | 1 (3.03%) | 1 (6.25%) |
| Hypertension | 0 (0%) | 0 (0%) |
| Hypocalcemia | 0 (0%) | 0 (0%) |
| Hypoglycemia | 1 (3.03%) | 2 (12.5%) |
| Hypokalemia | 2 (6.06%) | 1 (6.25%) |
| Hyponatremia | 0 (0%) | 0 (0%) |
| Hypophosphatemia | 4 (12.12%) | 1 (6.25%) |
| Influenza | 1 (3.03%) | 0 (0%) |
| Injection site erythema | 4 (12.12%) | 0 (0%) |
| Injection site induration | 0 (0%) | 0 (0%) |
| Injection site itching | 0 (0%) | 0 (0%) |
| Injection site pain | 2 (6.06%) | 1 (6.25%) |
| Injection site pruritus | 0 (0%) | 0 (0%) |
| Injection site swelling | 1 (3.03%) | 0 (0%) |
| Injury | 0 (0%) | 0 (0%) |
| Insect bite | 0 (0%) | 0 (0%) |
| Iron deficiency anemia | 1 (3.03%) | 0 (0%) |

| Event | Vaccine (N = 33) | Placebo (N = 16) |
|----------------------------|-------------------------|-------------------------|
| Knee pain | 0 (0%) | 0 (0%) |
| Laryngitis | 0 (0%) | 0 (0%) |
| Local swelling | 0 (0%) | 0 (0%) |
| Lymph node tenderness | 0 (0%) | 0 (0%) |
| Lymphocyte count increased | 0 (0%) | 0 (0%) |
| Muscle ache | 0 (0%) | 0 (0%) |
| Muscle strain | 0 (0%) | 0 (0%) |
| Myalgia | 2 (6.06%) | 1 (6.25%) |
| Nasal congestion | 0 (0%) | 0 (0%) |
| Nausea | 1 (3.03%) | 0 (0%) |
| Neutrophil count decreased | 1 (3.03%) | 1 (6.25%) |
| Oral pain | 1 (3.03%) | 0 (0%) |
| Peripheral neuropathy | 0 (0%) | 0 (0%) |
| Productive cough | 0 (0%) | 0 (0%) |
| Pruritic rash | 1 (3.03%) | 0 (0%) |
| Pruritus | 0 (0%) | 0 (0%) |
| Rash | 0 (0%) | 0 (0%) |
| Rhinorrhea | 0 (0%) | 0 (0%) |
| Sinusitis | 1 (3.03%) | 0 (0%) |
| Skin hyperpigmentation | 0 (0%) | 0 (0%) |
| Skin induration | 0 (0%) | 0 (0%) |
| Sore throat | 2 (6.06%) | 0 (0%) |
| Systolic hypertension | 0 (0%) | 0 (0%) |
| Tenderness | 0 (0%) | 0 (0%) |
| Tooth extraction | 1 (3.03%) | 0 (0%) |
| Torn bicep tendon | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | Placebo (N = 16) |
|-----------------------------------|-------------------------|-------------------------|
| Upper respiratory tract infection | 0 (0%) | 0 (0%) |
| Urinary frequency | 0 (0%) | 0 (0%) |
| Urinary tract infection | 0 (0%) | 0 (0%) |
| Urine WBC increased | 0 (0%) | 0 (0%) |
| Urticaria | 0 (0%) | 0 (0%) |
| Vertigo | 0 (0%) | 0 (0%) |
| Vitamin D deficiency | 0 (0%) | 0 (0%) |
| Vomiting | 1 (3.03%) | 0 (0%) |
| WBC decreased | 0 (0%) | 1 (6.25%) |
| WBC increased | 0 (0%) | 0 (0%) |

Table 6 : Occurrence of Grade 3 Events by Treatment Group

| Event | Vaccine (N = 33) | Placebo (N = 16) |
|--------------------------------------|-------------------------|-------------------------|
| Abdominal cramps | 0 (0%) | 0 (0%) |
| Abdominal pain | 0 (0%) | 0 (0%) |
| Absolute neutrophil count, decreased | 1 (3.03%) | 1 (6.25%) |
| Acute sinusitis | 0 (0%) | 0 (0%) |
| ALT increased | 0 (0%) | 0 (0%) |
| Anxiety | 0 (0%) | 0 (0%) |
| Arthralgia | 0 (0%) | 0 (0%) |
| AST increased | 0 (0%) | 0 (0%) |
| Bilirubin total high | 0 (0%) | 0 (0%) |
| Blood eosinophils increased | 0 (0%) | 0 (0%) |
| Bradycardia | 1 (3.03%) | 0 (0%) |
| BUN increased | 0 (0%) | 0 (0%) |
| Campylobacter | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | Placebo (N = 16) |
|---------------------------|-------------------------|-------------------------|
| Candida vaginitis | 0 (0%) | 0 (0%) |
| Chills | 0 (0%) | 0 (0%) |
| Common cold | 0 (0%) | 0 (0%) |
| Constipation | 0 (0%) | 0 (0%) |
| Coryza | 0 (0%) | 0 (0%) |
| CPK increased | 1 (3.03%) | 3 (18.75%) |
| Creatine kinase | 0 (0%) | 0 (0%) |
| Creatine kinase high | 0 (0%) | 1 (6.25%) |
| Creatinine increased | 0 (0%) | 0 (0%) |
| Dermatitis | 1 (3.03%) | 0 (0%) |
| Diaphoresis | 0 (0%) | 0 (0%) |
| Diarrhea | 0 (0%) | 0 (0%) |
| Difficulty sleeping | 0 (0%) | 0 (0%) |
| Dry cough | 0 (0%) | 0 (0%) |
| Eczema | 0 (0%) | 0 (0%) |
| Elevated liver enzymes | 0 (0%) | 0 (0%) |
| Elevated serum creatinine | 0 (0%) | 0 (0%) |
| Eosinophilia | 0 (0%) | 0 (0%) |
| Erythema | 0 (0%) | 0 (0%) |
| Eyelid Stye | 0 (0%) | 0 (0%) |
| Fatigue | 0 (0%) | 0 (0%) |
| Fever | 0 (0%) | 0 (0%) |
| Feverish | 0 (0%) | 0 (0%) |
| Gastritis | 0 (0%) | 0 (0%) |
| Headache | 0 (0%) | 0 (0%) |
| Hematuria | 2 (6.06%) | 0 (0%) |

| Event | Vaccine (N = 33) | Placebo (N = 16) |
|----------------------------|-------------------------|-------------------------|
| Hemoglobin decreased | 0 (0%) | 0 (0%) |
| Hyperglycemia | 0 (0%) | 0 (0%) |
| Hypernatremia | 1 (3.03%) | 0 (0%) |
| Hypertension | 0 (0%) | 0 (0%) |
| Hypocalcemia | 0 (0%) | 0 (0%) |
| Hypoglycemia | 2 (6.06%) | 1 (6.25%) |
| Hypokalemia | 0 (0%) | 1 (6.25%) |
| Hyponatremia | 0 (0%) | 0 (0%) |
| Hypophosphatemia | 0 (0%) | 0 (0%) |
| Influenza | 0 (0%) | 0 (0%) |
| Injection site erythema | 1 (3.03%) | 0 (0%) |
| Injection site induration | 0 (0%) | 0 (0%) |
| Injection site itching | 1 (3.03%) | 0 (0%) |
| Injection site pain | 0 (0%) | 0 (0%) |
| Injection site pruritus | 0 (0%) | 0 (0%) |
| Injection site swelling | 0 (0%) | 0 (0%) |
| Injury | 0 (0%) | 0 (0%) |
| Insect bite | 0 (0%) | 0 (0%) |
| Iron deficiency anemia | 0 (0%) | 0 (0%) |
| Knee pain | 0 (0%) | 0 (0%) |
| Laryngitis | 0 (0%) | 0 (0%) |
| Local swelling | 0 (0%) | 0 (0%) |
| Lymph node tenderness | 0 (0%) | 0 (0%) |
| Lymphocyte count increased | 0 (0%) | 0 (0%) |
| Muscle ache | 0 (0%) | 0 (0%) |
| Muscle strain | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | Placebo (N = 16) |
|-----------------------------------|-------------------------|-------------------------|
| Myalgia | 0 (0%) | 0 (0%) |
| Nasal congestion | 0 (0%) | 0 (0%) |
| Nausea | 0 (0%) | 0 (0%) |
| Neutrophil count decreased | 0 (0%) | 0 (0%) |
| Oral pain | 0 (0%) | 0 (0%) |
| Peripheral neuropathy | 0 (0%) | 0 (0%) |
| Productive cough | 0 (0%) | 0 (0%) |
| Pruritic rash | 1 (3.03%) | 0 (0%) |
| Pruritus | 0 (0%) | 0 (0%) |
| Rash | 0 (0%) | 1 (6.25%) |
| Rhinorrhea | 0 (0%) | 0 (0%) |
| Sinusitis | 0 (0%) | 0 (0%) |
| Skin hyperpigmentation | 0 (0%) | 0 (0%) |
| Skin induration | 0 (0%) | 0 (0%) |
| Sore throat | 0 (0%) | 0 (0%) |
| Systolic hypertension | 0 (0%) | 0 (0%) |
| Tenderness | 0 (0%) | 0 (0%) |
| Tooth extraction | 0 (0%) | 0 (0%) |
| Torn bicep tendon | 1 (3.03%) | 0 (0%) |
| Upper respiratory tract infection | 0 (0%) | 0 (0%) |
| Urinary frequency | 0 (0%) | 0 (0%) |
| Urinary tract infection | 1 (3.03%) | 1 (6.25%) |
| Urine WBC increased | 0 (0%) | 0 (0%) |
| Urticaria | 1 (3.03%) | 0 (0%) |
| Vertigo | 0 (0%) | 1 (6.25%) |
| Vitamin D deficiency | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | Placebo (N = 16) |
|---------------|-------------------------|-------------------------|
| Vomiting | 0 (0%) | 0 (0%) |
| WBC decreased | 0 (0%) | 0 (0%) |
| WBC increased | 0 (0%) | 0 (0%) |

Table 7 : Occurrence of Grade 4 Events by Treatment Group

| Event | Vaccine (N = 33) | Placebo (N = 16) |
|--------------------------------------|-------------------------|-------------------------|
| Abdominal cramps | 0 (0%) | 0 (0%) |
| Abdominal pain | 0 (0%) | 0 (0%) |
| Absolute neutrophil count, decreased | 0 (0%) | 0 (0%) |
| Acute sinusitis | 0 (0%) | 0 (0%) |
| ALT increased | 0 (0%) | 0 (0%) |
| Anxiety | 0 (0%) | 0 (0%) |
| Arthralgia | 0 (0%) | 0 (0%) |
| AST increased | 0 (0%) | 0 (0%) |
| Bilirubin total high | 0 (0%) | 0 (0%) |
| Blood eosinophils increased | 0 (0%) | 0 (0%) |
| Bradycardia | 0 (0%) | 0 (0%) |
| BUN increased | 0 (0%) | 0 (0%) |
| Campylobacter | 0 (0%) | 0 (0%) |
| Candida vaginitis | 0 (0%) | 0 (0%) |
| Chills | 0 (0%) | 0 (0%) |
| Common cold | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | Placebo (N = 16) |
|---------------------------|-------------------------|-------------------------|
| Constipation | 0 (0%) | 0 (0%) |
| Coryza | 0 (0%) | 0 (0%) |
| CPK increased | 2 (6.06%) | 0 (0%) |
| Creatine kinase | 0 (0%) | 0 (0%) |
| Creatine kinase high | 0 (0%) | 0 (0%) |
| Creatinine increased | 0 (0%) | 0 (0%) |
| Dermatitis | 0 (0%) | 0 (0%) |
| Diaphoresis | 0 (0%) | 0 (0%) |
| Diarrhea | 0 (0%) | 0 (0%) |
| Difficulty sleeping | 0 (0%) | 0 (0%) |
| Dry cough | 0 (0%) | 0 (0%) |
| Eczema | 0 (0%) | 0 (0%) |
| Elevated liver enzymes | 0 (0%) | 0 (0%) |
| Elevated serum creatinine | 0 (0%) | 0 (0%) |
| Eosinophilia | 0 (0%) | 0 (0%) |
| Erythema | 0 (0%) | 0 (0%) |
| Eyelid Stye | 0 (0%) | 0 (0%) |
| Fatigue | 0 (0%) | 0 (0%) |
| Fever | 0 (0%) | 0 (0%) |
| Feverish | 0 (0%) | 0 (0%) |
| Gastritis | 0 (0%) | 0 (0%) |
| Headache | 0 (0%) | 0 (0%) |
| Hematuria | 0 (0%) | 0 (0%) |
| Hemoglobin decreased | 0 (0%) | 0 (0%) |
| Hyperglycemia | 0 (0%) | 0 (0%) |
| Hypernatremia | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | Placebo (N = 16) |
|----------------------------|-------------------------|-------------------------|
| Hypertension | 0 (0%) | 0 (0%) |
| Hypocalcemia | 0 (0%) | 0 (0%) |
| Hypoglycemia | 0 (0%) | 0 (0%) |
| Hypokalemia | 0 (0%) | 0 (0%) |
| Hyponatremia | 0 (0%) | 0 (0%) |
| Hypophosphatemia | 0 (0%) | 0 (0%) |
| Influenza | 0 (0%) | 0 (0%) |
| Injection site erythema | 0 (0%) | 0 (0%) |
| Injection site induration | 0 (0%) | 0 (0%) |
| Injection site itching | 0 (0%) | 0 (0%) |
| Injection site pain | 0 (0%) | 0 (0%) |
| Injection site pruritus | 0 (0%) | 0 (0%) |
| Injection site swelling | 0 (0%) | 0 (0%) |
| Injury | 0 (0%) | 0 (0%) |
| Insect bite | 0 (0%) | 0 (0%) |
| Iron deficiency anemia | 0 (0%) | 0 (0%) |
| Knee pain | 0 (0%) | 0 (0%) |
| Laryngitis | 0 (0%) | 0 (0%) |
| Local swelling | 0 (0%) | 0 (0%) |
| Lymph node tenderness | 0 (0%) | 0 (0%) |
| Lymphocyte count increased | 0 (0%) | 0 (0%) |
| Muscle ache | 0 (0%) | 0 (0%) |
| Muscle strain | 0 (0%) | 0 (0%) |
| Myalgia | 0 (0%) | 0 (0%) |
| Nasal congestion | 0 (0%) | 0 (0%) |
| Nausea | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | Placebo (N = 16) |
|-----------------------------------|-------------------------|-------------------------|
| Neutrophil count decreased | 0 (0%) | 0 (0%) |
| Oral pain | 0 (0%) | 0 (0%) |
| Peripheral neuropathy | 0 (0%) | 0 (0%) |
| Productive cough | 0 (0%) | 0 (0%) |
| Pruritic rash | 0 (0%) | 0 (0%) |
| Pruritus | 0 (0%) | 0 (0%) |
| Rash | 0 (0%) | 0 (0%) |
| Rhinorrhea | 0 (0%) | 0 (0%) |
| Sinusitis | 0 (0%) | 0 (0%) |
| Skin hyperpigmentation | 0 (0%) | 0 (0%) |
| Skin induration | 0 (0%) | 0 (0%) |
| Sore throat | 0 (0%) | 0 (0%) |
| Systolic hypertension | 0 (0%) | 0 (0%) |
| Tenderness | 0 (0%) | 0 (0%) |
| Tooth extraction | 0 (0%) | 0 (0%) |
| Torn bicep tendon | 0 (0%) | 0 (0%) |
| Upper respiratory tract infection | 0 (0%) | 0 (0%) |
| Urinary frequency | 0 (0%) | 0 (0%) |
| Urinary tract infection | 0 (0%) | 0 (0%) |
| Urine WBC increased | 0 (0%) | 0 (0%) |
| Urticaria | 0 (0%) | 0 (0%) |
| Vertigo | 0 (0%) | 0 (0%) |
| Vitamin D deficiency | 0 (0%) | 0 (0%) |
| Vomiting | 0 (0%) | 0 (0%) |
| WBC decreased | 0 (0%) | 0 (0%) |
| WBC increased | 0 (0%) | 0 (0%) |

Table 8 : Occurrence of Max Grade Events Per Subject which are Unrelated to Treatment by Treatment Group

Note : In Tables 8-12, multiple occurrences of the same max grade event type with different relatedness are included in the respective table

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|--------------------------------------|------------------|---------|---------------|--------------|--------------|---------|------------------|---------|--------------|---------|--------------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Abdominal cramps | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Abdominal pain | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Absolute neutrophil count, decreased | 31 (93.94%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) |
| Acute sinusitis | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| ALT increased | 31 (93.94%) | 0 (0%) | 2 (6.06%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Anxiety | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Arthralgia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| AST increased | 29 (87.88%) | 0 (0%) | 4 (12.12%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Bilirubin total high | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Blood eosinophils increased | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Bradycardia | 31 (93.94%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| BUN increased | 32 (96.97%) | 0 (0%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Campylobacter | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Candida vaginitis | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Chills | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|---------------------------|------------------|---------|--------------|--------------|--------------|--------------|------------------|---------|--------------|--------------|---------------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Common cold | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Constipation | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Coryza | 31 (93.94%) | 0 (0%) | 1 (3.03%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| CPK increased | 28 (84.85%) | 0 (0%) | 0 (0%) | 3 (9.09%) | 1 (3.03%) | 1 (3.03%) | 10 (62.5%) | 0 (0%) | 1 (6.25%) | 2 (12.5%) | 3 (18.75%) | 0 (0%) |
| Creatine kinase | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Creatine kinase high | 31 (93.94%) | 0 (0%) | 0 (0%) | 2 (6.06%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Creatinine increased | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Dermatitis | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Diaphoresis | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Diarrhea | 32 (96.97%) | 0 (0%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Difficulty sleeping | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Dry cough | 31 (93.94%) | 0 (0%) | 2 (6.06%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Eczema | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Elevated liver enzymes | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Elevated serum creatinine | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Eosinophilia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Erythema | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|----------------------|------------------|---------|---------------|---------------|--------------|---------|------------------|---------|--------------|--------------|--------------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Eyelid Styte | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Fatigue | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Fever | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Feverish | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Gastritis | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Headache | 30 (90.91%) | 0 (0%) | 2 (6.06%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hematuria | 29 (87.88%) | 0 (0%) | 2 (6.06%) | 0 (0%) | 2 (6.06%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hemoglobin decreased | 23 (69.7%) | 0 (0%) | 6 (18.18%) | 4 (12.12%) | 0 (0%) | 0 (0%) | 13 (81.25%) | 0 (0%) | 2 (12.5%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| Hyperglycemia | 30 (90.91%) | 0 (0%) | 0 (0%) | 3 (9.09%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) |
| Hypernatremia | 27 (81.82%) | 0 (0%) | 4 (12.12%) | 1 (3.03%) | 1 (3.03%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypertension | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypocalcemia | 31 (93.94%) | 0 (0%) | 2 (6.06%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypoglycemia | 28 (84.85%) | 0 (0%) | 3 (9.09%) | 0 (0%) | 2 (6.06%) | 0 (0%) | 13 (81.25%) | 0 (0%) | 1 (6.25%) | 1 (6.25%) | 1 (6.25%) | 0 (0%) |
| Hypokalemia | 31 (93.94%) | 0 (0%) | 1 (3.03%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 1 (6.25%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| Hyponatremia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypophosphatemia | 28 (84.85%) | 0 (0%) | 1 (3.03%) | 4 (12.12%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| Influenza | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|----------------------------|------------------|---------|--------------|--------------|---------|---------|------------------|---------|--------------|---------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Injection site erythema | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site induration | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site itching | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site pain | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site pruritus | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site swelling | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injury | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Insect bite | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Iron deficiency anemia | 32 (96.97%) | 0 (0%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Knee pain | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Laryngitis | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Local swelling | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Lymph node tenderness | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Lymphocyte count increased | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Muscle ache | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Muscle strain | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Myalgia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|----------------------------|------------------|---------|--------------|--------------|---------|---------|------------------|---------|--------------|---------|--------------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Nasal congestion | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Nausea | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Neutrophil count decreased | 29 (87.88%) | 0 (0%) | 3 (9.09%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Oral pain | 32 (96.97%) | 0 (0%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Peripheral neuropathy | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Productive cough | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Pruritic rash | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Pruritus | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Rash | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) |
| Rhinorrhea | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Sinusitis | 32 (96.97%) | 0 (0%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Skin hyperpigmentation | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Skin induration | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Sore throat | 31 (93.94%) | 0 (0%) | 1 (3.03%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Systolic hypertension | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Tenderness | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Tooth extraction | 32 (96.97%) | 0 (0%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|-----------------------------------|------------------|---------|--------------|---------|--------------|---------|------------------|---------|--------------|--------------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Torn bicep tendon | 32 (96.97%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Upper respiratory tract infection | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urinary frequency | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urinary tract infection | 32 (96.97%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urine WBC increased | 31 (93.94%) | 0 (0%) | 2 (6.06%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urticaria | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Vertigo | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Vitamin D deficiency | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Vomiting | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| WBC decreased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| WBC increased | 31 (93.94%) | 0 (0%) | 2 (6.06%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |

Table 9 : Occurrence of Max Grade Events Per Subject which are Unlikely Related to Treatment by Treatment

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|--------------------------------------|------------------|---------|--------------|---------|---------|---------|------------------|---------|--------------|---------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Abdominal cramps | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Abdominal pain | 31 (93.94%) | 0 (0%) | 2 (6.06%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Absolute neutrophil count, decreased | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Acute sinusitis | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| ALT increased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Anxiety | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Arthralgia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| AST increased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Bilirubin total high | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Blood eosinophils increased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Bradycardia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| BUN increased | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Campylobacter | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Candida vaginitis | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Chills | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Common cold | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Constipation | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|---------------------------|------------------|---------|----------------|--------------|--------------|--------------|------------------|---------|----------------|--------------|--------------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Coryza | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| CPK increased | 31 (93.94%) | 0 (0%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 1 (3.03%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| Creatine kinase | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| Creatine kinase high | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) |
| Creatinine increased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Dermatitis | 32 (96.97%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Diaphoresis | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Diarrhea | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Difficulty sleeping | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Dry cough | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Eczema | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Elevated liver enzymes | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Elevated serum creatinine | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Eosinophilia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Erythema | 4 (12.12%) | 0 (0%) | 29 (87.88%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Eyelid Styte | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Fatigue | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|---------------------------|------------------|---------|---------------|--------------|--------------|---------|------------------|---------|--------------|--------------|--------------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Fever | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Feverish | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Gastritis | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Headache | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hematuria | 32 (96.97%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) |
| Hemoglobin decreased | 27 (81.82%) | 0 (0%) | 5 (15.15%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hyperglycemia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypernatremia | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| Hypertension | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypocalcemia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypoglycemia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypokalemia | 31 (93.94%) | 0 (0%) | 1 (3.03%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) |
| Hyponatremia | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypophosphatemia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Influenza | 32 (96.97%) | 0 (0%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site erythema | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site induration | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|----------------------------|------------------|---------|----------------|--------------|---------|---------|------------------|---------|----------------|---------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Injection site itching | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site pain | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site pruritus | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site swelling | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injury | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Insect bite | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Iron deficiency anemia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Knee pain | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Laryngitis | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Local swelling | 2 (6.06%) | 0 (0%) | 31 (93.94%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Lymph node tenderness | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Lymphocyte count increased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Muscle ache | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Muscle strain | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Myalgia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Nasal congestion | 31 (93.94%) | 0 (0%) | 2 (6.06%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Nausea | 30 (90.91%) | 0 (0%) | 2 (6.06%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|-----------------------------------|------------------|---------|--------------|--------------|--------------|---------|------------------|---------|--------------|--------------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Neutrophil count decreased | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| Oral pain | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Peripheral neuropathy | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Productive cough | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Pruritic rash | 30 (90.91%) | 0 (0%) | 1 (3.03%) | 1 (3.03%) | 1 (3.03%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Pruritus | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Rash | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Rhinorrhea | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Sinusitis | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Skin hyperpigmentation | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Skin induration | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Sore throat | 31 (93.94%) | 0 (0%) | 1 (3.03%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Systolic hypertension | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Tenderness | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Tooth extraction | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Torn bicep tendon | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Upper respiratory tract infection | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|-------------------------|------------------|---------|--------------|--------------|---------|---------|------------------|---------|--------------|---------|--------------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Urinary frequency | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urinary tract infection | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) |
| Urine WBC increased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urticaria | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Vertigo | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (6.25%) | 0 (0%) |
| Vitamin D deficiency | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Vomiting | 31 (93.94%) | 0 (0%) | 1 (3.03%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| WBC decreased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| WBC increased | 30 (90.91%) | 0 (0%) | 3 (9.09%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

Table 10 : Occurrence of Max Grade Events Per Subject which are Possibly Related to Treatment by Treatment Group

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|--------------------------------------|------------------|---------|--------------|---------|---------|---------|------------------|---------|---------|---------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Abdominal cramps | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Abdominal pain | 30 (90.91%) | 0 (0%) | 3 (9.09%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Absolute neutrophil count, decreased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Acute sinusitis | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| ALT increased | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|-----------------------------|------------------|---------|--------------|---------|---------|---------|------------------|---------|--------------|---------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Anxiety | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Arthralgia | 31 (93.94%) | 0 (0%) | 2 (6.06%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| AST increased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Bilirubin total high | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Blood eosinophils increased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Bradycardia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| BUN increased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Campylobacter | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Candida vaginitis | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Chills | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Common cold | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Constipation | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Coryza | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| CPK increased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Creatine kinase | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Creatine kinase high | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Creatinine increased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|---------------------------|------------------|---------|---------------|--------------|---------|---------|------------------|---------|--------------|---------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Dermatitis | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Diaphoresis | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Diarrhea | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Difficulty sleeping | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Dry cough | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Eczema | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Elevated liver enzymes | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Elevated serum creatinine | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Eosinophilia | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Erythema | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Eyelid Stye | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Fatigue | 27 (81.82%) | 0 (0%) | 6 (18.18%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Fever | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Feverish | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Gastritis | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Headache | 24 (72.73%) | 0 (0%) | 6 (18.18%) | 3 (9.09%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hematuria | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|---------------------------|------------------|---------|--------------|---------|---------|---------|------------------|---------|---------|---------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Hemoglobin decreased | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hyperglycemia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypernatremia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypertension | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypocalcemia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypoglycemia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypokalemia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hyponatremia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypophosphatemia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Influenza | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site erythema | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site induration | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site itching | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site pain | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site pruritus | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site swelling | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injury | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|----------------------------|------------------|---------|--------------|--------------|---------|---------|------------------|---------|--------------|---------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Insect bite | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Iron deficiency anemia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Knee pain | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Laryngitis | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Local swelling | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Lymph node tenderness | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Lymphocyte count increased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Muscle ache | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Muscle strain | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Myalgia | 31 (93.94%) | 0 (0%) | 1 (3.03%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Nasal congestion | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Nausea | 31 (93.94%) | 0 (0%) | 2 (6.06%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Neutrophil count decreased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Oral pain | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Peripheral neuropathy | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Productive cough | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Pruritic rash | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|-----------------------------------|------------------|---------|--------------|---------|--------------|---------|------------------|---------|--------------|---------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Pruritus | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Rash | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 2 (12.5%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Rhinorrhea | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Sinusitis | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Skin hyperpigmentation | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Skin induration | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Sore throat | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Systolic hypertension | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Tenderness | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Tooth extraction | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Torn bicep tendon | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Upper respiratory tract infection | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urinary frequency | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urinary tract infection | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urine WBC increased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urticaria | 32 (96.97%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Vertigo | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|----------------------|------------------|---------|---------|---------|---------|---------|------------------|---------|--------------|---------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Vitamin D deficiency | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Vomiting | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| WBC decreased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| WBC increased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

Table 11 : Occurrence of Max Grade Events Per Subject which are Probably Related to Treatment by Treatment Group

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|--------------------------------------|------------------|---------|---------|--------------|---------|---------|------------------|---------|---------|---------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Abdominal cramps | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Abdominal pain | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Absolute neutrophil count, decreased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Acute sinusitis | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| ALT increased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Anxiety | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Arthralgia | 31 (93.94%) | 0 (0%) | 0 (0%) | 2 (6.06%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|-----------------------------|------------------|---------|--------------|--------------|---------|---------|------------------|---------|--------------|---------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| AST increased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Bilirubin total high | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Blood eosinophils increased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Bradycardia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| BUN increased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Campylobacter | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Candida vaginitis | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Chills | 29 (87.88%) | 0 (0%) | 1 (3.03%) | 3 (9.09%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Common cold | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Constipation | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Coryza | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| CPK increased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Creatine kinase | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Creatine kinase high | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Creatinine increased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Dermatitis | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Diaphoresis | 32 (96.97%) | 0 (0%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|---------------------------|------------------|---------|---------------|--------------|---------|---------|------------------|---------|--------------|--------------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Diarrhea | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Difficulty sleeping | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Dry cough | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Eczema | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Elevated liver enzymes | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Elevated serum creatinine | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Eosinophilia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Erythema | 32 (96.97%) | 0 (0%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Eyelid Styte | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Fatigue | 25 (75.76%) | 0 (0%) | 5 (15.15%) | 3 (9.09%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 1 (6.25%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| Fever | 32 (96.97%) | 0 (0%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Feverish | 27 (81.82%) | 0 (0%) | 3 (9.09%) | 3 (9.09%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 0 (0%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Gastritis | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Headache | 28 (84.85%) | 0 (0%) | 3 (9.09%) | 2 (6.06%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hematuria | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hemoglobin decreased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hyperglycemia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|---------------------------|------------------|---------|--------------|---------|---------|---------|------------------|---------|---------|---------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Hypernatremia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypertension | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypocalcemia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypoglycemia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypokalemia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hyponatremia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypophosphatemia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Influenza | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site erythema | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site induration | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site itching | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site pain | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site pruritus | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site swelling | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injury | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Insect bite | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Iron deficiency anemia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|----------------------------|------------------|---------|---------------|--------------|---------|---------|------------------|---------|--------------|--------------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Knee pain | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Laryngitis | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Local swelling | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Lymph node tenderness | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Lymphocyte count increased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Muscle ache | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Muscle strain | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Myalgia | 26 (78.79%) | 0 (0%) | 6 (18.18%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 14 (87.5%) | 0 (0%) | 1 (6.25%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| Nasal congestion | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Nausea | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Neutrophil count decreased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Oral pain | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Peripheral neuropathy | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Productive cough | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Pruritic rash | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Pruritus | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Rash | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|-----------------------------------|------------------|---------|--------------|---------|---------|---------|------------------|---------|---------|---------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Rhinorrhea | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Sinusitis | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Skin hyperpigmentation | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Skin induration | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Sore throat | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Systolic hypertension | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Tenderness | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Tooth extraction | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Torn bicep tendon | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Upper respiratory tract infection | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urinary frequency | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urinary tract infection | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urine WBC increased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urticaria | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Vertigo | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Vitamin D deficiency | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Vomiting | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|---------------|------------------|---------|---------|---------|---------|---------|------------------|---------|---------|---------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| WBC decreased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| WBC increased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

Table 12 : Occurrence of Max Grade Events Per Subject which are Definitely Related to Treatment by Treatment Group

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|--------------------------------------|------------------|---------|---------|---------|---------|---------|------------------|---------|---------|---------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Abdominal cramps | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Abdominal pain | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Absolute neutrophil count, decreased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Acute sinusitis | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| ALT increased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Anxiety | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Arthralgia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| AST increased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Bilirubin total high | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Blood eosinophils increased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Bradycardia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| BUN increased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|------------------------|------------------|---------|---------|---------|---------|---------|------------------|---------|---------|---------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Campylobacter | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Candida vaginitis | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Chills | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Common cold | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Constipation | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Coryza | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| CPK increased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Creatine kinase | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Creatine kinase high | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Creatinine increased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Dermatitis | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Diaphoresis | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Diarrhea | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Difficulty sleeping | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Dry cough | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Eczema | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Elevated liver enzymes | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|---------------------------|------------------|---------|--------------|---------|---------|---------|------------------|---------|---------|---------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Elevated serum creatinine | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Eosinophilia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Erythema | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Eyelid Stye | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Fatigue | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Fever | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Feverish | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Gastritis | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Headache | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hematuria | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hemoglobin decreased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hyperglycemia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypnatremia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypertension | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypocalcemia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypoglycemia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypokalemia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|----------------------------|------------------|--------------|----------------|--------------|--------------|---------|------------------|--------------|---------------|--------------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Hyponatremia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Hypophosphatemia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Influenza | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site erythema | 22 (66.67%) | 3 (9.09%) | 4 (12.12%) | 3 (9.09%) | 1 (3.03%) | 0 (0%) | 14 (87.5%) | 1 (6.25%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site induration | 31 (93.94%) | 1 (3.03%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site itching | 26 (78.79%) | 0 (0%) | 6 (18.18%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site pain | 18 (54.55%) | 0 (0%) | 13 (39.39%) | 2 (6.06%) | 0 (0%) | 0 (0%) | 12 (75%) | 0 (0%) | 3 (18.75%) | 1 (6.25%) | 0 (0%) | 0 (0%) |
| Injection site pruritus | 31 (93.94%) | 0 (0%) | 2 (6.06%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injection site swelling | 22 (66.67%) | 3 (9.09%) | 7 (21.21%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 15 (93.75%) | 1 (6.25%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Injury | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Insect bite | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Iron deficiency anemia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Knee pain | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Laryngitis | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Local swelling | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Lymph node tenderness | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Lymphocyte count increased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|----------------------------|------------------|---------|--------------|---------|---------|---------|------------------|---------|---------|---------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Muscle ache | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Muscle strain | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Myalgia | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Nasal congestion | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Nausea | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Neutrophil count decreased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Oral pain | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Peripheral neuropathy | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Productive cough | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Pruritic rash | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Pruritus | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Rash | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Rhinorrhea | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Sinusitis | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Skin hyperpigmentation | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Skin induration | 32 (96.97%) | 0 (0%) | 1 (3.03%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Sore throat | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

| Event | Vaccine (N = 33) | | | | | | Placebo (N = 16) | | | | | |
|-----------------------------------|------------------|---------|---------|---------|---------|---------|------------------|---------|---------|---------|---------|---------|
| | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 | No Sx | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Systolic hypertension | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Tenderness | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Tooth extraction | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Torn bicep tendon | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Upper respiratory tract infection | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urinary frequency | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urinary tract infection | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urine WBC increased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Urticaria | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Vertigo | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Vitamin D deficiency | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Vomiting | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| WBC decreased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| WBC increased | 33 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 16 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |

Table 13 : Occurrence of “Worst” Relatedness to Treatment Per Subject by Treatment

| | Vaccine (N = 33) | Placebo (N = 16) |
|--------------------|------------------|------------------|
| Definitely Related | 22 (66.67%) | 4 (25%) |
| Probably Related | 1 (3.03%) | 2 (12.5%) |

| | | |
|------------------|------------|------------|
| Possibly Related | 4 (12.12%) | 2 (12.5%) |
| Unlikely Related | 6 (18.18%) | 7 (43.75%) |
| Unrelated | 0 (0%) | 0 (0%) |
| No AEs | 0 (0%) | 1 (6.25%) |

Table 14 : Number of Subjects with Event Per Group and One-Sided Fisher's Exact Test P-Values Comparing Vaccine to Placebo

| Event | Vaccine: Adjuvant + AGS-V or AGS-V (N = 33) | Placebo (N = 16) | Fisher's Exact P-value |
|--------------------------------------|--|------------------|------------------------|
| Abdominal cramps | 1 | 0 | 0.67 |
| Abdominal pain | 5 | 1 | 0.35 |
| Absolute neutrophil count, decreased | 3 | 1 | 0.61 |
| Acute sinusitis | 0 | 1 | 1 |
| ALT increased | 3 | 0 | 0.3 |
| Anxiety | 1 | 0 | 0.67 |
| Arthralgia | 4 | 0 | 0.19 |
| AST increased | 4 | 1 | 0.47 |
| Bilirubin total high | 1 | 0 | 0.67 |
| Blood eosinophils increased | 1 | 0 | 0.67 |
| Bradycardia | 2 | 0 | 0.45 |
| BUN increased | 2 | 1 | 0.75 |
| Campylobacter | 0 | 1 | 1 |
| Candida vaginitis | 0 | 2 | 1 |
| Chills | 5 | 1 | 0.35 |
| Common cold | 1 | 1 | 0.9 |
| Constipation | 0 | 1 | 1 |
| Coryza | 2 | 1 | 0.75 |
| CPK increased | 7 | 6 | 0.94 |
| Creatine kinase | 0 | 1 | 1 |

| Event | Vaccine: Adjuvant + AGS-V or AGS-V (N = 33) | Placebo (N = 16) | Fisher's Exact P-value |
|---------------------------|--|-------------------------|-------------------------------|
| Creatine kinase high | 2 | 1 | 0.75 |
| Creatinine increased | 1 | 0 | 0.67 |
| Dermatitis | 1 | 0 | 0.67 |
| Diaphoresis | 4 | 1 | 0.47 |
| Diarrhea | 2 | 1 | 0.75 |
| Difficulty sleeping | 1 | 0 | 0.67 |
| Dry cough | 2 | 0 | 0.45 |
| Eczema | 1 | 0 | 0.67 |
| Elevated liver enzymes | 1 | 0 | 0.67 |
| Elevated serum creatinine | 1 | 0 | 0.67 |
| Eosinophilia | 1 | 0 | 0.67 |
| Erythema | 30 | 15 | 0.81 |
| Eyelid Stye | 1 | 0 | 0.67 |
| Fatigue | 13 | 4 | 0.25 |
| Fever | 1 | 2 | 0.97 |
| Feverish | 8 | 3 | 0.48 |
| Gastritis | 0 | 1 | 1 |
| Headache | 15 | 4 | 0.14 |
| Hematuria | 4 | 3 | 0.85 |
| Hemoglobin decreased | 15 | 5 | 0.26 |
| Hyperglycemia | 3 | 2 | 0.81 |
| Hypernatremia | 7 | 3 | 0.58 |
| Hypertension | 1 | 0 | 0.67 |
| Hypocalcemia | 2 | 0 | 0.45 |
| Hypoglycemia | 5 | 3 | 0.77 |
| Hypokalemia | 4 | 3 | 0.85 |

| Event | Vaccine: Adjuvant + AGS-V or AGS-V (N = 33) | Placebo (N = 16) | Fisher's Exact P-value |
|----------------------------|--|-------------------------|-------------------------------|
| Hyponatremia | 1 | 0 | 0.67 |
| Hypophosphatemia | 5 | 2 | 0.59 |
| Influenza | 1 | 0 | 0.67 |
| Injection site erythema | 11 | 2 | 0.11 |
| Injection site induration | 2 | 0 | 0.45 |
| Injection site itching | 8 | 0 | 0.03* |
| Injection site pain | 15 | 4 | 0.14 |
| Injection site pruritus | 2 | 0 | 0.45 |
| Injection site swelling | 11 | 1 | 0.04* |
| Injury | 1 | 0 | 0.67 |
| Insect bite | 0 | 1 | 1 |
| Iron deficiency anemia | 1 | 0 | 0.67 |
| Knee pain | 1 | 0 | 0.67 |
| Laryngitis | 0 | 1 | 1 |
| Local swelling | 31 | 15 | 0.7 |
| Lymph node tenderness | 1 | 0 | 0.67 |
| Lymphocyte count increased | 1 | 0 | 0.67 |
| Muscle ache | 2 | 0 | 0.45 |
| Muscle strain | 1 | 0 | 0.67 |
| Myalgia | 8 | 5 | 0.81 |
| Nasal congestion | 3 | 1 | 0.61 |
| Nausea | 5 | 2 | 0.59 |
| Neutrophil count decreased | 5 | 3 | 0.77 |
| Oral pain | 1 | 0 | 0.67 |
| Peripheral neuropathy | 0 | 1 | 1 |
| Productive cough | 1 | 0 | 0.67 |

| Event | Vaccine: Adjuvant + AGS-V or AGS-V (N = 33) | Placebo (N = 16) | Fisher's Exact P-value |
|-----------------------------------|--|-------------------------|-------------------------------|
| Pruritic rash | 3 | 0 | 0.3 |
| Pruritus | 1 | 0 | 0.67 |
| Rash | 0 | 3 | 1 |
| Rhinorrhea | 1 | 1 | 0.9 |
| Sinusitis | 1 | 0 | 0.67 |
| Skin hyperpigmentation | 2 | 0 | 0.45 |
| Skin induration | 1 | 0 | 0.67 |
| Sore throat | 3 | 1 | 0.61 |
| Systolic hypertension | 1 | 0 | 0.67 |
| Tenderness | 1 | 0 | 0.67 |
| Tooth extraction | 1 | 0 | 0.67 |
| Torn bicep tendon | 1 | 0 | 0.67 |
| Upper respiratory tract infection | 1 | 0 | 0.67 |
| Urinary frequency | 0 | 1 | 1 |
| Urinary tract infection | 1 | 1 | 0.9 |
| Urine WBC increased | 2 | 0 | 0.45 |
| Urticaria | 1 | 0 | 0.67 |
| Vertigo | 0 | 1 | 1 |
| Vitamin D deficiency | 1 | 0 | 0.67 |
| Vomiting | 2 | 0 | 0.45 |
| WBC decreased | 0 | 2 | 1 |
| WBC increased | 3 | 1 | 0.61 |

* Indicates one-sided Fisher's Exact p-value < 0.1

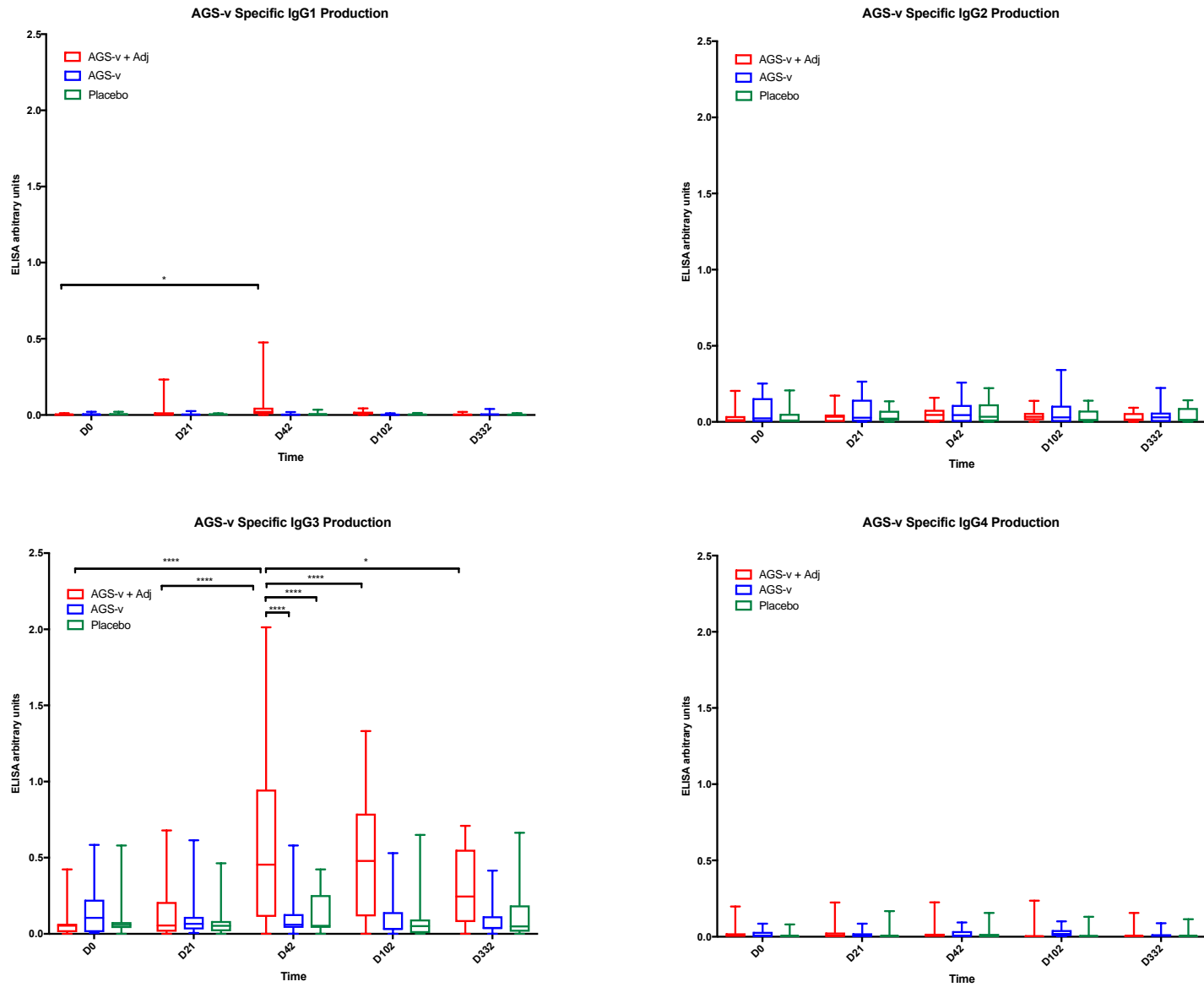
| | | | | | | | | |
|------------------------------|---------|---|--------|---|---|---|---------|---|
| Adjusted p-values | | | | | | | | |
| AGS-v + Adjuvant vs. AGS-v | 0.48 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| AGS-v vs. Placebo | 0.0072* | 1 | 1 | 1 | 1 | 1 | 0.36 | 1 |
| AGS-v + Adjuvant vs. Placebo | 0.0166* | 1 | 0.0518 | 1 | 1 | 1 | 0.0185* | 1 |

*denotes significant between group differences at the .05 level

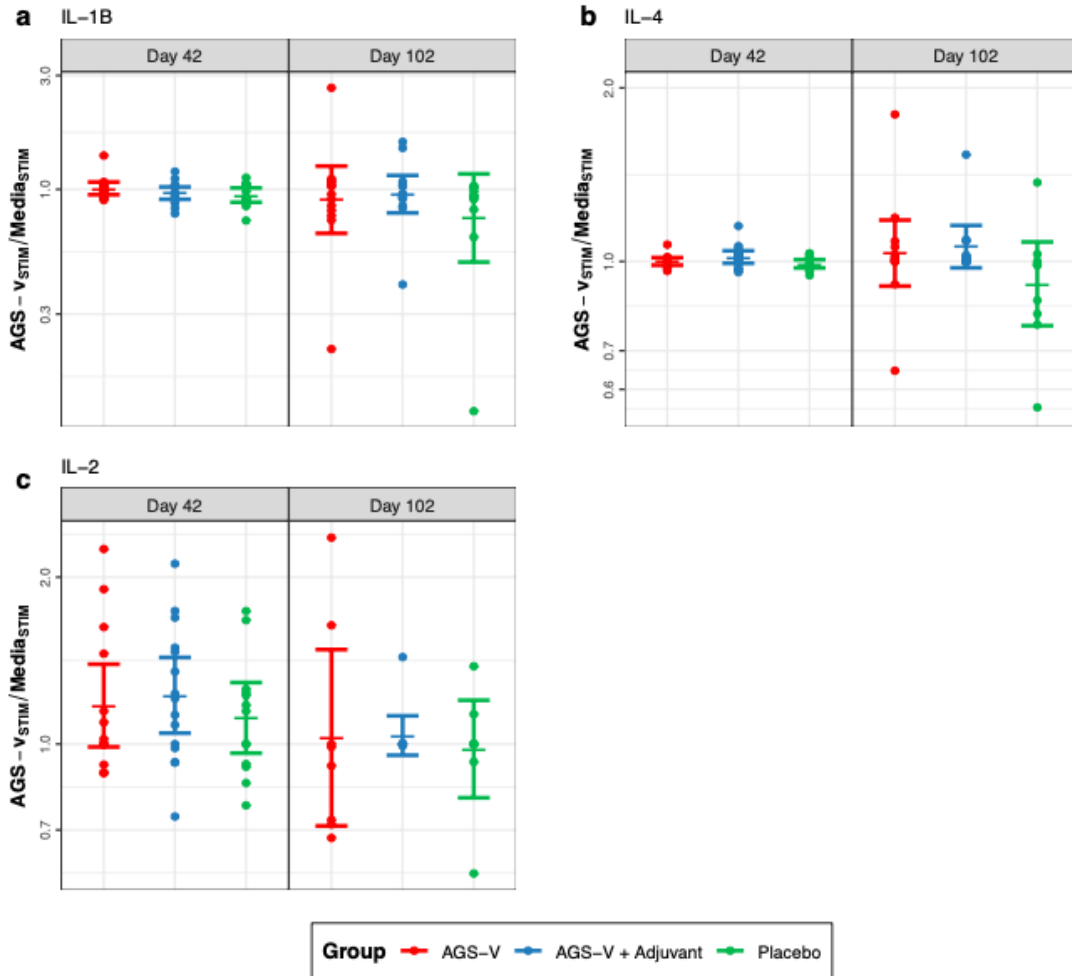
Supplementary Table 6. Mosquito survival and fecundity

| Mean (SD) | # Eggs | # Pupae (out of 100 eggs) | # Adults (out of 100 eggs) | % Eggs Become Pupae | % Pupae Become Adults |
|------------------------------|-----------------|---------------------------|----------------------------|---------------------|-----------------------|
| AGS-V | 706 (123.75) | 78.93 (13.08) | 69.13 (14.07) | 11.59 (3.26) | 88.12 (12.8) |
| AGS-V + Adjuvant | 673.88 (221.29) | 79.62 (14.86) | 75.25 (13.55) | 15.56 (13.58) | 94.96 (6.86) |
| Placebo | 663 (165.51) | 81.93 (9.08) | 78.53 (9.52) | 13.76 (6.49) | 95.77 (2.88) |
| Adjusted p-values | | | | | |
| AGS-V + Adjuvant vs. AGS-V | 1 | 1 | 1 | 1 | 1 |
| AGS-V vs. Placebo | 1 | 1 | 0.588 | 1 | 0.585 |
| AGS-V + Adjuvant vs. Placebo | 1 | 1 | 1 | 1 | 1 |

Supplementary Figure 1. Vaccine-specific antibody IgG isotypes in 3 treatment groups



Supplementary Figure 2. Cellular response to vaccine peptides for remaining three cytokines



Supplementary Figure 3. Baseline and Follow-up Immunity to *Anopheles gambiae* and *Aedes aegypti* salivary gland homogenate is unchanged across all three groups.

