Supplemental Tables

Table 1. Treatments assigned for patients enrolled on Mel44 trial in 4 study arms

|  |  |  |  |
| --- | --- | --- | --- |
| Mel 44 Study Arm  | Peptides to stimulate CD8 T cells | Peptides to stimulate CD4 T cells | Cyclophosphamide pre-treatment |
| A | 12MP | Tet | No |
| B | 12MP | Tet | Yes |
| C | 12MP | 6MHP | No |
| D | 12MP | 6MHP | Yes |
| 12MP = 12 class 1 major histocompatibility complex-restricted melanoma peptides stimulating CD8+ T cells; Tet = nonspecific tetanus helper peptide;6MHP = six melanoma-associated class 2 major histocompatibility complex-restricted melanoma helper peptides stimulating CD4+ T cells |

Table 2. TRAE counts in Mel44 clinical vaccine trial, organized by grade, vaccine arm and biological sex

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|   |   | **Total\*** | **Male**  | **Female** | **p-value** |
| **Overall** | *Patient Numbers (% of total)* | *170* | *114 (67%)* | *56 (33%)* |  |
| N without TRAEs | 1 (1%) | 0 (0%) | 1 (2%) | 0.421 |
| N with grade 1 TRAEs | 26 (15%) | 20 (18%) | 6 (11%) |
| N with grade 2 TRAEs | 124 (73%) | 82 (72%) | 42 (75%) |
| N with grade 3 TRAEs | 18 (11%) | 11 (10%) | 7 (12%) |
| N with grade 4 TRAEs | 1 (1%) | 1 (1%) | 0 (0%) |
| **Arm A** | *Patient Numbers (% of total)* | *41* | *28 (68%)* | *13 (32%)* |   |
| N with grade 1 TRAEs or no TRAEs | 5 (12%) | 5 (18%) | 0 (0%) | 0.309  |
| N with grade 2 TRAEs | 30 (73%) | 19 (68%) | 11 (85%) |
| N with grade 3 or 4 TRAEs | 6 (15%) | 4 (14%) | 2 (15%) |
| **Arm B** | *Patient Numbers (% of total)* | *43* | *26 (60%)* | *17 (40%)* |  |
| N with grade 1 TRAEs or no TRAEs | 2 (5%) | 1 (4%) | 1 (6%) | 0.730  |
| N with grade 2 TRAEs | 33 (77%) | 19 (73%) | 14 (82%) |
| N with grade 3 or 4 TRAEs | 8 (19%) | 6 (23%) | 2 (12%) |
| **Arm C** | *Patient Numbers (% of total)* | *42* | *29 (69%)* | *13 (31%)* |   |
| N with grade 1 TRAEs or no TRAEs | 12 (29%) | 6 (21%) | 6 (46%) | 0.177  |
| N with grade 2 TRAEs | 28 (67%) | 22 (76%) | 6 (46%) |
| N with grade 3 or 4 TRAEs | 2 (5%) | 1 (3%) | 1 (8%) |
| **Arm D** | *Patient Numbers (% of total)* | *44* | *31 (70%)* | *13 (30%)* |   |
| N with grade 1 TRAEs or no TRAEs | 8 (18%) | 8 (26%) | 0 (0%) | 0.052  |
| N with grade 2 TRAEs | 33 (75%) | 22 (71%) | 11 (85%) |
| N with grade 3 or 4 TRAEs | 3 (7%) | 1 (3%) | 2 (15%) |

\*Total TRAEs were previously reported, but the breakdown by gender was not reported.