Table S2: G001 schedule of procedures.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Visit Number |  | 2 | | 3 |  |  | 4 | 5 | 6 | 7 | 7A | 8 | 9 | | 10 | |  | |  | |  |
| Study Month | -2.5 | -1 | | 0 |  |  |  |  |  | 2 |  |  |  | | 4 | | 6 | | 81 | | 14 |
| Study Week | -10 | -4 | | 0 | 0.5 | 1 | 2 | 3 | 4 | 8 | 92 | 102 | 112 | | 16 | | 20 | | 32 | | 56 |
| Study Day | -70 | -28 | | 0 | D3 | 7 | 14 | 21 | 28 | 56 | 63 | 70 | 77 | | 112 | | 140 | | 224 | | 392 |
| Visit Windows (Days) |  | -42 to +7 | | 0 | ± 1 | +3 | ± 3 | ± 3 | ± 3 | ± 7 | -2 to +1 | ± 4 | ± 3 | | ± 7 | | ± 7 | | ± 14 | | +28 |
| Investigational Product/Placebo |  |  | | X |  |  |  |  |  | X |  |  |  | |  | |  | |  | |  |
| Leukapheresis |  | X | |  |  |  |  |  |  |  |  | X |  | |  | |  | |  | |  |
| FNA |  |  | |  |  |  |  | X |  |  |  |  | X | |  | |  | |  | |  |
| Telephone Contact |  |  | |  | X | X |  |  |  |  |  |  |  | |  | | X | |  | |  |
| Informed Consent/AOU | X |  | |  |  |  |  |  |  |  |  |  |  | |  | |  | |  | |  |
| HIV Risk Assessment | X |  | |  |  |  |  |  |  |  |  |  |  | |  | |  | |  | | X |
| HIV Risk Reduction Counseling | X |  | |  |  |  |  |  |  |  |  |  |  | |  | |  | | X | | X |
| HIV-test and Counseling | X |  | |  |  |  |  |  |  |  |  |  |  | |  | |  | | X4 | | X |
| Family Planning Counseling | X |  | | X |  |  |  |  |  | X |  |  |  | | X | |  | | X | |  |
| Social Impact Assessment |  |  | |  |  |  |  |  |  |  |  |  |  | |  | |  | |  | | X |
| Comprehensive Medical History | X |  | |  |  |  |  |  |  |  |  |  |  | |  | |  | |  | |  |
| Interim Medical History |  | X | | X | X | X | X | X | X | X | X | X | X | | X | | X | | X | | X |
| Concomitant Medications | X | X | | X |  |  | X | X | X | X | X | X | X | | X5 | |  | |  | |  |
| General Physical Exam | X |  | |  |  |  |  |  |  |  |  |  |  | |  | |  | | X | |  |
| Directed Physical Exam |  | X | | X |  |  | X | X | X | X | X | X | X | | X | |  | |  | | X |
| Weight | X | X | |  |  |  |  |  |  |  |  | X |  | |  | |  | |  | |  |
| Height | X |  | |  |  |  |  |  |  |  |  |  |  | |  | |  | |  | |  |
| Vital Signs | X | X | | X |  |  | X | X | X | X | X | X | X | | X | |  | | X | | X |
| Cervical & Axillary Lymph Nodes6 |  |  | | X |  |  | X7 |  |  | X | X |  |  | |  | |  | |  | |  |
| Local & Systemic Reactogenicity |  |  | | X | X | X | X |  |  | X | X |  |  | |  | |  | |  | |  |
| Adverse Events |  |  | | X | X | X | X | X | X | X | X | X | X | | X5 | |  | |  | |  |
| Serious Adverse Events and/or pIMD | X | X | | X | X | X | X | X | X | X | X | X | X | | X | | X | | X | | X8 |
| Screening labs9 | X |  | |  |  |  |  |  |  |  |  |  |  | |  | |  | |  | |  |
| Safety labs10 | X |  | | X |  |  | X |  |  | X |  | X |  | | X | |  | | X | |  |
| Urine dipstick | X |  | | X |  |  |  |  |  | X |  |  |  | | X | |  | | X | |  |
| Pregnancy test | X | X | | X |  |  |  | X |  | X |  | X | X | | X | |  | | X | |  |
| Serum binding antibody |  |  | | X |  |  | X |  | X | X |  | X |  | | X | |  | |  | |  |
| B-cell sorting (PBMCs) |  | X | |  |  |  |  |  | X | X |  | X |  | | X | |  | |  | |  |
| B-cell sorting (FNA) |  |  | |  |  |  |  | X |  |  |  |  | X | |  | |  | |  | |  |
| Ag-specific CD4 T cells (PBMCs) |  | X | |  |  |  |  |  |  |  |  | X |  | |  | |  | |  | |  |
| Plasmablasts |  |  | |  |  |  |  |  |  |  | X |  |  | |  | |  | |  | |  |
| Serum neutralization |  |  | | X |  |  | X |  |  | X |  | X |  | | X | |  | |  | |  |
| ­­ |  |  |  |  |  |  |  |  |  |  |  |  | |  | |  | |  | |  | |

*1 Early Termination (ET): Procedures to be performed at ET are the same as Month 8, except for HIV end-of-study testing, HIV risk and social impact assessment (Month 14).*

*2 Study days 63, 70 and 77 must be counted from 7,14 and 21 days respectively from time of the 2nd vaccination.*

*3 The window for the first leukapheresis can occur any time after completing successful screening up to 3 weeks prior to the first vaccination. The preferred target is at least 4 weeks before first vaccination.*

*4 If HIV infected, conduct ET visit, and see SOM for details.*

*5 New adverse events and concomitant medications collected only through Day 28 after second vaccination.*

*6 At each vaccination visit and during the reactogenicity period, an assessment of cervical and axillary lymph nodes is performed. If there are findings, continue to assess at later visits until resolved.*

*7 After the first vaccination, cervical and axillary lymph nodes will be assessed at the next clinic visit.*

*8 Follow-up for SAEs or potential immune-mediated diseases (pIMDs) with additional clinical follow-up, if indicated.*

*9 Screening labs include testing for hepatitis B, hepatitis C, syphilis, HIV testing and safety labs.*

*10 Safety labs include complete blood count with automated differential, platelet count, ALT, AST and creatinine.*