

TABLE 2 TRIALS OF PREVENTIVE HIV/AIDS VACCINES WORLDWIDE (AUGUST 2006)

| PROTOCOL # | START DATE | SPONSOR, FUNDER, DEVELOPER | TRIAL SITE(S) | VACCINE(S) | # OF VOLUNTEERS | CLADE |
|------------------------|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------|
| PHASE III | | | | | | |
| RV 144 | Oct-03 | USMHRP, MoPH Thailand, Aventis, Vaxgen | Thailand | Prime: canary pox viral vector with <i>env</i> and <i>gag-pol</i> Boost: Env protein (gp120 subunits) | 16,402 | B, A/E |
| TEST-OF-CONCEPT | | | | | | |
| HVTN 502/Merck 023 | Dec-04 | DAIDS, HVTN, Merck | US, Canada, Peru, Dominican Republic, Haiti, Puerto Rico, Australia, Brazil, Jamaica | Adenovirus vector with <i>gag, pol, nef</i> | 3,000 | B |
| PHASE II | | | | | | |
| IAVI A002 | Nov-05 | Children's Hospital of Pennsylvania, Columbus Children's Research Center, Indian Council of Medical Research, National AIDS Control Organization, Targeted Genetics Corp. | South Africa, Uganda, Zambia | AAV2 (adeno-associated virus type 2) vector with <i>gag, pol, ΔRT</i> | 91 | C |
| HVTN 204 | Sep-05 | DAIDS, HVTN, VRC, Vical, GenVec | US, Brazil, South Africa, Haiti, Jamaica | Prime: DNA vaccine with <i>gag, pol, nef + env</i> Boost: Adenovirus vector with <i>gag, pol + env</i> | 480 | B A, B, C |
| ANRS VAC 18 | Sep-04 | ANRS, Aventis | France | 5 lipopeptides with CTL epitopes from <i>gag, nef, pol</i> | 132 | B |
| PHASE I/II | | | | | | |
| RV 172 | May-06 | NIH, WRAIR, VRC | Kenya, Uganda, Tanzania | Prime: DNA vaccine with <i>gag, pol, nef + env</i> Boost: Adenovirus vector with <i>gag, pol + env</i> | 324 | B A, B, C |
| C060301 | Feb-04 | FIT Biotech, IAVI | Finland | DNA vaccine with <i>nef, rev, tat, gag, pol, env</i> , CTL epitopes | 28 | B |
| PHASE I | | | | | | |
| VRC 011 | Apr-06 | NIAID, VRC | US | DNA vaccine with <i>gag, pol, nef + env</i> or Adenovirus vector with <i>gag, pol + env</i> | 60 | A, B, C |
| HVTN 065 | Apr-06 | DAIDS, HVTN, VRC, GeoVax | US | Prime: DNA plasmid with <i>gag, pro, RT, env, tat, rev, vpu</i> Boost: Modified vaccinia Ankara (MVA) vector with <i>gag, pol, env</i> | 120 | B |
| IAVI D001 | Feb-06 | IAVI, Therion | India | Modified vaccinia Ankara (MVA) with <i>env, gag, tat-rev, nef-RT</i> | 32 | C |
| HVTN 064 | Jan-06 | DAIDS, HVTN, Pharmexa-Epimmune | US, Peru | Recombinant protein vaccine with <i>gag, pol, vpr, nef</i> and DNA vaccine with protein containing T-helper epitopes from <i>env, gag, pol, vpu</i> | 120 | B |
| HVTN 068 | Feb-06 | DAIDS, HVTN, VRC | US | Adenovirus vector with <i>gag, pol + env</i> or DNA vaccine with <i>gag, pol, nef + env</i> followed by adenoviral boost | 66 | B A, B, C |
| HIVIS 02 | Jan-06 | Karolinska Institute, Swedish Institute for Infectious Disease Control, WRAIR | Sweden | Modified vaccinia Ankara (MVA) viral vector with <i>env, gag, and pol</i> to volunteers from HIVIS 01 | 38 | A, E |
| IAVI V001 | Nov-05 | IAVI, NIAID, VRC | Rwanda, Kenya | Prime: DNA vaccine with <i>gag, pol, env</i> Boost: Adenovirus vector with <i>gag, pol, env</i> | 104 | A, B, C |
| RV 158 | Nov-05 | WRAIR, NIH | US, Thailand | Modified vaccinia Ankara (MVA) viral vector with gp160, <i>gag</i> and <i>pol</i> | 48 | A, E |
| HVTN 063 | Sep-05 | DAIDS, HVTN, Wyeth | US, Brazil | Prime: Genevax Gag-2692 +/- IL-15 DNA Boost: Genevax Gag-2692 + IL-12 DNA or IL-15 DNA | 120 | B |
| HVTN 060 | Aug-05 | DAIDS, HVTN, Wyeth | US, Thailand | Prime: Genevax Gag-2692 +/- IL-12 DNA adjuvant Boost: DNA plasmids with <i>gag</i> or RC529-SE and GM-CSF with <i>env, gag, nef</i> | 156 | B |

TRIALS OF PREVENTIVE HIV/AIDS VACCINES WORLDWIDE (AUGUST 2006) *continued*

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|--------------------|------------|--------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|---------------|
| HVTN 054 | Apr-05 | DAIDS, HVTN, VRC | US | Adenovirus vector with <i>gag, pol + env</i> | 48 | B A, B, C |
| VRC 008 | Apr-05 | NIAID, VRC | US | Prime: DNA vaccine with <i>gag, pol, nef + env</i> Boost: Adenovirus vector with <i>gag, pol + env</i> | 40 | B A, B, C |
| N/A | Mar-05 | Changchun BCHT, Guangxi CDC | China | Prime: DNA vaccine Boost: recombinant adenovirus vector | 49 | C |
| HIVIS 01 | Feb-05 | Karolinska Institute, Swedish Institute for Infectious Disease Control, Vecura | Sweden | Intramuscular or intradermal injections of plasmid DNA with HIV genes <i>env, rev, gag, and RT</i> | 40 | A, B, C |
| EuroVacc 02 | Feb-05 | EU, Imperial College London, UK MRC Clinical Trials Unit, EuroVacc | UK, Switzerland | Vaccinia vector with <i>gag, pol, nef, env</i> | 40 | C |
| N/A | Feb-05 | St. Jude, NIH | US | Recombinant HIV-1 multi-envelope DNA plasmid vaccine with <i>env</i> | 6 | A, B, C, D, E |
| RV 156 | Jan-05 | NIAID, HVTN, VRC, USMHRP, Makerere U. | Uganda | Prime: DNA vaccine with <i>gag, pol, nef + env</i> Boost: Adenovirus vector with <i>gag, pol + env</i> | | B A, B, C |
| IAVI C002 | Jan-05 | IAVI, ADARC | US | Modified vaccinia Ankara (MVA) vector with <i>env/gag-pol, nef-tat</i> | 48 | C |
| HVTN 059 | Oct-04 | HVTN, SAAVI, Alphavax | US, South Africa, Botswana | VEE (Venezuelan equine encephalitis) vector with <i>gag</i> | 96 | C |
| HVTN 055 | Sept-04 | DAIDS, HVTN, Therion | US, Brazil | Prime: Modified vaccinia Ankara (MVA) viral vector with <i>env, gag, tat, rev, nef, pol</i> Boost: Fowlpox viral vector (FPV) with same genes as prime | 150 | B |
| HVTN 056 | Apr-04 | DAIDS, HVTN, Wyeth | US | Conserved CTL epitopes from <i>gag, nef</i> and helper T epitopes from <i>env, gag</i> in adjuvant (RC329-SE), with or without cytokine (GM-CSF) | 96 | B |
| HVTN 050/Merck 018 | Jan-04 | NIAID, HVTN, Merck | Thailand, Brazil, Haiti, Puerto Rico, South Africa, US, Malawi, Peru | Adenovirus vector with <i>gag</i> | 435 | B |
| HVTN 049 | Dec-03 | DAIDS, HVTN, Chiron | US | Prime: DNA vaccine with <i>gag, env</i> attached to microparticles Boost: Env protein (oligomeric gp140) + adjuvant (MF59) | 96 | B |
| HVTN 044 | Dec-03 | DAIDS, HVTN, VRC | US | DNA vaccine with <i>gag, pol, nef + env</i> with or without cytokine (IL-2) adjuvant | 70 | B A, B, C |
| IAVI A001 | Dec-03 | Columbus Children's Research Center, Indian Council of Medical Research, National AIDS Control Organization, IAVI, Targeted Genetics | Belgium, Germany, India | AAV2 (adeno-associated virus type 2) vector with <i>gag, pol, ΔRT</i> | 50 | C |
| B011; RV 138 | Jul-02 | WRRAIR | US | Canarypox viral vector with <i>env, gag, pol</i> | 36 | B |

KEY

ABL Advanced BioScience Laboratories
 ADARC Aaron Diamond AIDS Research Center
 ANRS Agence Nationale de Recherches sur le Sida (France)
 DAIDS Division of AIDS
 HVTN HIV Vaccine Trials Network
 IAVI International AIDS Vaccine Initiative
 MoPH Ministry of Public Health
 NIAID National Institute of Allergy and Infectious Diseases

NIH National Institutes of Health
 SAAVI South African AIDS Vaccine Initiative
 UMMS University of Massachusetts Medical School
 USMHRP United States Military HIV Research Program
 VRC Vaccine Research Center
 WRRAIR Walter Reed Army Institute for Research
 ZEHRP Zambia Emory HIV Research Project