HVTN 703/ HPTN 081

HIV Prevention Trials Network

HIV VACCINE TRIALS NETWORK

A phase 2b study to evaluate the safety and efficacy of VRC01 broadly neutralizing monoclonal antibody in reducing acquisition of HIV-1 infection

Inclusion Criteria

General and Demographic Criteria

- Age 18 – 50 years
- Access to a participating CRS
- Ability & Willingness to provide informed consent

General and Demographic Criteria

- Agrees not to enrol in another study
- Volunteer demonstrates understanding of this study
- Good general health
  - As shown by medical history, physical exam, and screening laboratory tests

HIV-Related Criteria

- **Willingness to receive HIV test results**
- **Willingness to discuss HIV infection risks and amenable to HIV risk reduction counselling**
- **In Africa, persons born Female (assigned female sex at birth) and identifying as a female**
  - Who, in the 6 months prior to randomization, has had vaginal and/or anal intercourse with a male partner.
  - All volunteers who have been in a monogamous relationship with an HIV-1 seronegative partner for > 1 year are excluded

Inclusion Criteria

- HIV uninfected, within 30 days prior to enrolment.
- Not pregnant
- Hemoglobin (Hgb) > 10.5 g/dL
- Platelets:≥ 100,000 cells/mm^3
- ALT <2.5 ULN
- Negative, trace, or 1+ urine protein by dipstick

Exclusion Criteria

General

- **Investigational research agents received within 30 days before first infusion**
- **Body mass index (BMI) ≥ 40 kg/m²**
- **Exclusion Criteria: Monoclonal antibodies and vaccines**
  - Previous receipt of humanized or human mAbs
  - HIV vaccine(s) received in a prior HIV vaccine trial

Immune System

- **Serious adverse reactions to VRC01 formulation components**
  - Such as sodium citrate, sodium chloride, and L-arginine hydrochloride
- **Autoimmune disease**
- **Immunodeficiency syndrome**

Clinically significant medical conditions

- **Any medical, psychiatric, occupational, or other condition**
  - in the judgment of the investigator, would interfere with, or serve as a contraindication to, protocol adherence, assessment of safety or infusion reactions, or a volunteer's ability to give informed consent.
- **Psychiatric condition that precludes compliance with the protocol**
- **Asthma**
- **Bleeding Disorder**

Clinically significant medical conditions

- Malignancy
- Seizure Disorder
- Angioedema
  - History of hereditary angioedema, acquired angioedema, or idiopathic angioedema.
- Organ or tissue transplantation
- Known hepatic or renal dysfunction

Clinically significant medical conditions

- **Clinically significant medical condition**
  - Physical examination findings, clinically significant abnormal laboratory results, or past medical history with clinically significant implications for current health.

Thank you