### Efficacy Trial

<table>
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<th>Status of select biomedical HIV prevention clinical trials</th>
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<tr>
<td><strong>Vaginal Ring</strong></td>
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<td>Dapivirine Ring (Monthly)</td>
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<td><strong>Oral PrEP</strong></td>
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#### Status of Preventive HIV Vaccine
- **ALVAC/gp120 w/MF59**
  - HVTN 702
  - Randomized controlled trial of ALVAC/gp120 prime-boost with MF59 adjuvant, six doses over 18 months; 5,400 men and women in South Africa; immunizations halted for non-efficacy; follow-up ongoing

- **Ad26/gp140 boost**
  - Imbokodo (HVTN 705/ HPX2008)
  - Randomized controlled trial of Ad26 prime with gp140 boost; four doses over 12 months; fully enrolled 2,600 women in Malawi, Mozambique, South Africa, Zambia, Zimbabwe

- **Ad26/clade C gp140 & mosaic gp140 boost**
  - Mosaic (HVTN 706/ HPX3002)
  - Randomized controlled trial of Ad26 prime with clade C and mosaic gp140 boost; ongoing in 3,800 MSM and transgender people in Argentina, Brazil, Italy, Mexico, Peru, Poland, Spain, US

#### Status of Oral PrEP
- **F/TAF (Daily pill)**
  - DISCOVER

- **Islatravir (Monthly pill)**
  - IMPOWER-22
  - Randomized controlled trial of monthly islatravir; ongoing in 4,500 women in the US

- **Lenacapavir (Every six months)**
  - PURPOSE 1
    - Trial of six-monthly injectable lenacapavir planned in 5,010 AGYW in South Africa and Uganda (alongside daily oral F/TAF)
  - PURPOSE 2
    - Trial of six-monthly injectable lenacapavir in 3,000 cisgender MSM, transgender women, transgender men, and gender non-binary individuals.

#### Status of Antibody
- **VRC01**
  - AMP (HVTN 704/ HPTN 085)
  - Randomized controlled trial of the VRC01 antibody infused every two months; ongoing in 2,700 MSM and transgender men & women in Brazil, Peru, Switzerland, US
  - Jan 2021: VRC01 did not significantly reduce the overall risk of HIV acquisition, but it reduced risk from HIV strains classified as highly-sensitive to VRC01.

- **AMP (HVTN 703/ HPTN 081)**
  - Randomized controlled trial of the VRC01 antibody infused every two months; ongoing in 1,900 women in Botswana, Kenya, Malawi, Mozambique, Tanzania, South Africa, Zimbabwe

#### Status of Oral PrEP and vaccine
- **PrEPVacc**
  - Randomized controlled trial of DNA-MVA-env or DNA-env with F/TAF or F/TDF, planned in 1668 participants in Mozambique, South Africa, Tanzania, Uganda

#### Status of Vaginal Ring
- **Dapivirine Ring (Monthly)**
  - July 2020: European Medicines Agency issues a positive opinion

#### Status of Oral PrEP
- **F/TAF (Daily pill)**
  - October 2019: FDA approves F/TAF for adults and adolescents who have no HIV risk from receptive vaginal sex

#### Status of Long-Acting Injectable
- **Cabotegravir (Every two months)**
  - HPTN 083
  - HPTN 084

- **Lenacapavir (Every six months)**
  - PURPOSE 1
  - PURPOSE 2

#### Status of Preventive HIV Vaccine
- **ALVAC/gp120 w/MF59**
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### Status of select biomedical HIV prevention clinical trials
- **Jan 2021**: WHO recommends as an additional prevention choice for women at substantial risk of HIV. Approval under review by a number of regulatory authorities.
- **Dec 2021**: FDA approves CAB-LA for PrEP in the US. Multiple applications under review with other regulatory bodies.
- **February 2020**: Trial stopped early for non-efficacy.

#### On hold
- Related lenacapavir studies showed lower lymphocyte and CD4+ T cell counts in some participants.
- Related islatravir studies showed lower lymphocyte and CD4+ T cell counts in some participants.
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## The Years Ahead in Biomedical HIV Prevention Research

This table provides an overview of the status of select biomedical HIV prevention clinical trials, including their years of investigation and key milestones.

**Vaginal Ring**
- Dapivirine Ring (Monthly)

**Oral PrEP**
- F/TAF (Daily pill)

**Islatravir (Monthly pill)**

**Long-Acting Injectable**
- Cabotegravir (Every two months)

**Lenacapavir (Every six months)**

**Preventive HIV Vaccine**
- ALVAC/gp120 w/MF59
- Ad26/gp140 boost
- Imbokodo (HVTN 705/ HPX2008)
- Ad26/clade C gp140 & mosaic gp140 boost
- Mosaic (HVTN 706/ HPX3002)

**Oral PrEP and vaccine**
- PrEPVacc

**Antibody**
- VRC01

This information is critical for understanding the current landscape of biomedical HIV prevention research and the potential future directions in the field.