MATRIX-001 Phase 1 Study of the TAF/EVG Fast-Dissolving Insert

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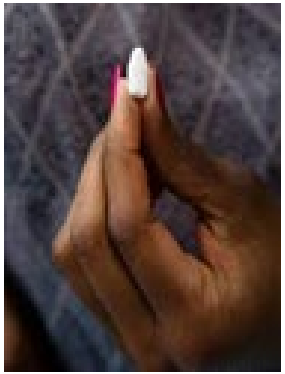
Advancing R&D of Innovative
HIV Prevention Products for Women

What is MATRIX-001?



- A Phase 1 study being developed to evaluate of the TAF/EVG fast-dissolving insert used vaginally
  - Will also evaluate user acceptability, how and where the two drugs are taken up in the body, and potential activity against HIV and herpes simplex virus (HSV)
- Will enroll 60 women at 3 trial sites in the U.S., Kenya (KEMRI) and South Africa (CAPRISA)
- Is the first study of the TAF/EVG fast-dissolving insert in African women
- The insert is being developed by CONRAD/ Eastern Virginia Medical School

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MATRIX-001 is the fourth study related to the TAV/EVG fast-dissolving insert

Previous studies evaluated:

- The safety and acceptability of a **placebo insert** (with no active drug) among 32 women in the US (CONRAD 134)
- The safety and acceptability of the active product with single use as a **vaginal insert** among 16 women in the US (CONRAD 146)
- The safety of two different doses of the active product used as a **rectal insert** among 20 participants in the US (MTN-039)
- Where and how the two drugs (TAF and EVG) are taken up in the body with vaginal use (CONRAD 146) and rectal use (MTN-039)

Why MATRIX-001?

- Researchers need to know about **the safety** of the TAF-EVG insert **with more frequent vaginal use** (not just one time)
- Need to understand **safety and acceptability in African women**, not just women in the US
- Will provide information about **where the drugs go in the body**– and **how long they remain there** – when used consecutive days as a vaginal insert, as well as insight into the product's **potential effectiveness** against HIV and HSV
- Study results will determine **whether the TAF/EVG insert should proceed to Phase 2 studies** to evaluate its safety and acceptability when used as designed – at or around the time of sex, and vaginally or rectally

Why MATRIX-001?

Women need more options!

The TAF/EVG fast-dissolving insert:

- Is the first (and only) on-demand product in clinical trials
- Currently, the only product designed to protect against both HIV and herpes simplex virus (HSV)
    - HSV is the most common cause of genital ulcers (which increases risk of acquiring HIV through sex) and the most prevalent STI worldwide
    - SSA is the most severely impacted region – with 80% of sexually active women likely to get HSV by age 35

How is the study currently designed?

- Women will be randomly assigned to use either the TAF/EVG fast-dissolving insert or an insert with no active drug
  - They will use their assigned product over the course of 2 weeks – at first, every day for 3 consecutive days; and then every other day (every 48 hours)
  - Product use will be timed so that it does not coincide with menstruation (women will begin the 2-week period shortly after menses)
  - After the 2-week product-use period, they will be followed for an additional week
- Safety will be assessed by physical exam and laboratory tests
- To assess how and where the drugs are taken up in the body, researchers will conduct laboratory tests of blood, vaginal fluid, rectal fluid and cervical tissue samples taken at different study visits
- Acceptability will be assessed through interviews and questionnaires

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Who may enroll in MATRIX-001?

To enroll in the study, women must :

- Be between the ages of 18-50
- Be in general good health
- Not be HIV-infected
- Not be pregnant or breastfeeding (an infant under 6 months of age)
- Use contraception (except for vaginal rings) and/or abstain from penile-vaginal sex during the 3-week study
- If in a relationship, be mutually monogamous, and her partner must not be known to have HIV or any other sexually transmitted infection

Informed consent

- Participants must provide informed consent to ensure they understand the potential risks and benefits of taking part in the study

What's involved in being in the study?

- As currently designed, participants will have 9 clinic visits over the course of the 3-week study
- At some clinic visits, study staff will conduct a physical and/or pelvic exam
- Other visits may involve answering questions about
  - what they think about the product
  - whether they are having any problems with inserting it or after insertion
  - whether they can feel the insert
- Blood, vaginal fluid, rectal fluid and vaginal tissue samples will be taken at different time points during the study:
  - 4 hours after the first insert
  - 1-3 days after the last insert

Ensuring the safety of participants

- Several measures will be in place to ensure the safety of participants, beginning at the site level
- An independent safety physician will monitor all "adverse events," and regular reviews of safety data will take place during the study
- Participants will stop using their assigned study product if there are any concerns

Current Status and Study Timelines

- The protocol is expected to be finalized by the end of this year (2022), and early next year, sites will seek regulatory and Institutional Review Board/Ethics Committee (IRB/EC) approvals to begin the study
- Pending approvals, the study is expected to start mid 2023 and be completed within 1 year, with results likely late 2024.

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