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HIV Prevention
Trials Network

Study Overview & Lessons Learned

HPTN 077

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Study Rationale

- HPTN 077 is a Phase IIa study designed to establish the safety, tolerability, and multiple-dose pharmacokinetics of GSK1265744 (cabotegravir) in low-risk HIV-uninfected men and women.

- Following small single-dose and multiple-dose studies of a long-acting Nano suspension formulation (744LA), this study is the next developmental investigation of the 744LA Nano suspension in healthy, HIV negative, low-risk for HIV acquisition men and women.
- While preventive and therapeutic efficacy have yet to be definitively established, the goal of the product development pathway (by way of planned future Phase 3 studies) to establish the efficacy, safety, and tolerability of 744LA for HIV prevention. A parallel developmental pathway is being pursued for HIV therapeutic use.

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Study Design and Duration

- Phase 2a, randomized, multi-site, two-arm, double-blind study of the safety, tolerability, pharmacokinetics, and acceptability of 744LA.

- Participants enrolled into two cohorts, and will begin an oral lead-in phase in which they will be randomized to receive daily oral 744 (30 mg tablets) or matching placebo for 4 weeks, followed by a one week washout period, to assess safety prior to receiving 744LA.

- Following final safety lab assessments from the oral regimen phase, participants will enter the injection phase and receive IM injections of 744LA or placebo at three time points at 12 week intervals in Cohort 1, and five time points at 4 and 8 week intervals in Cohort 2.

Study Population and Size

- 194 HIV-uninfected men and women

- Parallel studyconducted in the US in men who have sex with men

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Study Objectives

Primary Objective

- Evaluate the safety and tolerability of the injectable agent GSK1265744 long acting (744LA) injectable (800 mg dose administered at three time points at 12 week intervals), through Week 41 in HIV-uninfected men and women.
- Evaluate the safety and tolerability of the injectable agent GSK1265744 long acting (744LA) injectable (600 mg dose administered at two time points at 4 week intervals, followed by three time points at 8 week intervals), through Week 41 in HIV-uninfected men and women.
- Evaluate the safety and tolerability of GSK1265744 (daily oral 744 + 744LA) for 52 weeks of follow-up after final injection (each cohort will be analyzed separately)

Continued

- Evaluate the acceptability of 744LA injections
- Evaluate the effect of 744LA on sexual risk behavior by change from enrollment over time during the study period
- Evaluate HIV incidence and antiretroviral drug resistance, in participants who acquire HIV infection during the study

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Clinical Research Sites

- Rio de Jenero, Brazil
- Lilongwe, Malawi
- Vulindlela and Soweto, South Africa
- Chapel Hill, North Carolina; Los Angeles and San Francisco , California; and Washington, District of Columbia

Current Study Status

- Closed to Accrual, enrolled approximately 200 HIV-uninfected men and women in 8 cities.
- Due to latest information, study participants asked to stay in the study for additional 6 months.

Community Engagement

- CAB members debriefing
- Health facility debriefing
- Stake holders Meetings
- Chief’s debriefing
- Potential participants
- HTC centers

Lessons Learned

- The community accepted the injectable ARVs and took part in the study.
- Challenges with adherence to the oral drugs
- Community engagement is an ongoing process

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HPTN team, all stakeholders and all the participants who have made this study a success.

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Community Engagement is a

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