Medicines Control Authority of Zimbabwe

Clinical Trials Registry

PUBLIC TITLE/ACRONYM	GSK_ViiV_221163
Scientific Title	Long-Term Follow-Up of CAB LA for Participants in HPTN 083 and HPTN 084 CAB PrEP Studies at Risk of HIV Acquisition.

Primary Sponsor Details

Sponsors *	ViiV Healthcare UK Limited

Secondary Sponsor Details

Contact for Public Queries

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Countries of Recruitment *

Argentina, Botswana, Brazil, eSwatini (formerly Swaziland), Kenya, Malawi, Peru, South Africa, Thailand, Uganda, Vietnam, and Zimbabwe

Source of Funds	ViiV Healthcare UK Limited
Health Condition(s) or Problem(s) Studied *	HIV Prevention
Medicine Name *	CAB LA (Cabotegravir) Intra Muscular 600mg (200 mg/mL)
Quantity of medicine required *	13296

7.0 PRINCIPAL INCLUSION CRITERIA *

Participants must be currently enrolled and ongoing in one of the following studies:

- HPTN 084
- HPTN 084 adolescent and pregnancy sub-studies

Participants who have permanently withdrawn from prior CAB PrEP studies cannot enrol into this study.

Evidence of continued benefit (HIV negative and at risk) from CAB LA during participation in the parent study/sub-study.

Participants must have a nonreactive HIV test at Screening (rapid test, antigen/antibody test and HIV-1 RNA from the parent study/sub-study) and Day 1 (a rapid test and HIV Immunoassay [Antigen/Antibody test]).

Males and Females:
All participants who are engaging in sexual activity should be counselled on safer sexual practices including the use and benefit/risk of effective barrier methods (e.g., male condom) and on the risk of acquiring HIV and other STIs.

Females:
Cisgender female participants who are of childbearing potential and who are engaging in sexual activity that could lead to pregnancy, must talk to the investigator about recommended contraception options. Contraception will be optional in this study. Condoms are recommended in addition, because their appropriate use is the only contraception method effective for preventing HIV-1 transmission. Pregnant participants from the HPTN 084 study are eligible to enrol into this study if they meet all eligibility criteria.

Participant or caregiver/legal guardian is able and willing to provide signed informed consent as described in Section 11.1.4 of the protocol, which includes compliance with the requirements and restrictions listed in the consent form and in this protocol. Where applicable, participants must provide written assent.

7.1 PRINCIPAL EXCLUSION CRITERIA *

Concurrent conditions / medical history (includes liver function).

Participants who are currently enrolled in the eligible studies on the TDF/FTC arm are not eligible to enrol into this study. Participants receiving short-term oral TDF/FTC bridging may be enrolled following consultation with the Medical Monitor.

Previous permanent discontinuation from IP in the parent study/sub-study.

Known ALT >5 x ULN or ALT>3 x ULN and bilirubin >1.5 x ULN (with >35% direct bilirubin).

Participants with known hepatitis B infection at any time prior to entry (as evidence by a positive Hepatitis B virus surface antigen positive and/or quantifiable Hepatitis B DNA PCR).

Unstable liver disease (as defined by any of the following: presence of ascites, encephalopathy, coagulopathy, hypoalbuminemia, oesophageal or gastric varices, or persistent jaundice or cirrhosis), known biliary abnormalities (with the exception of hyperbilirubinemia or jaundice due to Gilbert's syndrome or asymptomatic gallstones or otherwise stable chronic liver disease per investigator).

Known history of cirrhosis with or without viral hepatitis co-infection.

Participant is currently participating in or has participated in a study (other than the studies listed in Inclusion Criteria 1) with a compound or device that is not commercially available within 30 days of signing informed consent, unless permission from the Medical Monitor is granted.

Presence of any history of allergy/sensitivity to any of the study drug.

Inflammatory skin conditions that compromise the safety of IM injections, per the discretion of the investigator. Mild skin conditions may not be exclusionary at the discretion of the investigator or designee.

Participant has a gluteal implant, tattoo or other dermatological condition overlying the buttock region which in the opinion of the investigator or designee may interfere with the injection or interpretation of ISRs.

Coagulopathy (primary or iatrogenic) which would contraindicate IM injection.

Use of any disallowed medications at time of screening

Anticipated need for HCV therapy with interferon or any drugs that have potential for adverse drug: drug interactions with study treatment throughout the entire study period.

Participant is unlikely to adhere to the study procedures, keep appointments, or is planning to relocate during the study.

Any condition (including but not limited to alcohol and drug use) that would, in the opinion of the site investigator, place the participant at an unacceptable risk of injury or render the participant unable to meet the requirements of the protocol.

7.2 PRIMARY END POINTS *

investigator, place the participant at an unacceptable risk of injury or render the participant unable tomeet the requirements of the protocol.

9.0 DESIGN OF THE TRIAL

Type of trial *	Opened
If controlled	
Randomised	No
Single Blind	
Double Blind	
Parallel group	
Cross over	
Other	
If yes to other, specify	
If controlled, specify the comparator	
Other medicinal product(s)	
Placebo	
Other	
If yes to other, specify	
Other	

Expected Number of participants in Zimbabwe *	554
Total enrolment in each site: (if competitive enrolment, state minimum and maximum number per site.) *	100-130
Total participants worldwide *	3500

Time period for the trial *	3 years or until CAB LA receives local regulatory approval (by country) and is available in those countries, or until other access occurs from another source