LAPaL
THE LONG-ACTING THERAPEUTICS PATENTS AND LICENCES DATABASE

Developed by

medicines patent pool

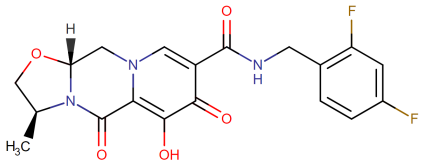
UNIVERSITY OF LIVERPOOL

CELT

Supported by

Unitaid
SAVE LIVES FASTER

leap



Cabotegravir LA (1M/2M)

Developer(s)

ViiV Healthcare

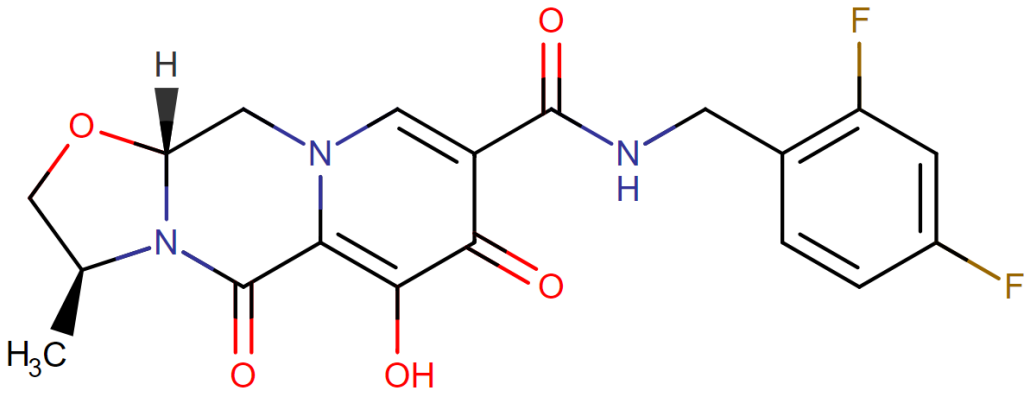
Originator

https://viivhealthcare.com/

United Kingdom

ViiV Healthcare is a pharmaceutical company that specializes in the development of therapies for HIV infection. The company is headquartered in Brentford in the United Kingdom and was initially formed in November 2009 as a part of a joint venture between GlaxoSmithKline and Pfizer.

Drug structure



Cabotegravir Chemical Structure

Sourced from DrugBank

Drug information

Associated long-acting platforms

Aqueous drug particle suspension

Administration route

Oral, Intramuscular

Therapeutic area(s)

HIV

Use case(s)

Pre-Exposure Prophylaxis (PrEP)
Treatment

Use of drug

Ease of administration

Administered by a nurse
Administered by a specialty health worker

User acceptance

Not provided

Dosage

Available dose and strength

600 mg/3 mL

Frequency of administration

Once monthly (Q1M); Two months once (Q2M)

Maximum dose

200 mg/mL

Recommended dosing regimen

Not provided

Additional comments

Not provided

Dosage link(s)

https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215499s000lbl.pdf

Drug information

Drug's link(s)

Not provided

Generic name

Cabotegravir

Brand name

Apretude, Vocabria

Compound type

Small molecule

Summary

Cabotegravir (CAB), also known as GSK1265744, is a HIV-1 integrase strand transfer inhibitor (INSTI) used for pre-exposure prophylaxis (PrEP) and the treatment of individuals infected with HIV. CAB is utilised in combination with Rilpivirine (a non-nucleoside reverse transcriptase inhibitor, NNRTI) for HIV treatment. Long-acting versions of CAB (CAB-LA) are currently administered once monthly or every-2-months as a intramuscular (IM) injection containing an extended-release drug particle nanosuspension, with an optional ~30 day oral-lead in period. CAB-LA administered by IM injection requires approximately one week to achieve maximal plasma drug concentration. CAB is metabolised in the body by the enzyme UGT1A1; with the average half-life of IM CAB-LA ranging from 5.6 to 11.5 weeks.

Approval status

CAB-LA (APRETUDE) 600mg/3mL extended-release IM injectable suspension single dose vials have received approval for use in HIV-1 PrEP for HIV-negative adults and adolescents weighing ≥ 35 kilograms who are at risk of infection. CAB-LA (VOCABRIA)

is used together with another medicine called rilpivirine (REKAMBYS) (or co-packed as a2-drug co-packaged product CABENUVA) as a complete regimen for the treatment to treat adults (and children, depending on approvals) living with human HIV-1. VOCABRIA is available as tablets to be taken by mouth and as a prolonged-release suspension for injection.

Regulatory authorities

CAB-LA has been designated as a Breakthrough Therapy by the USFDA, granted Extension of Indications approval by TGA Australia, and awarded European Marketing Authorization by the EMA. It is indicated for individuals without prior HIV-1 infection and devoid of any indications of drug resistance. Medicine Control Authority of Zimbabwe was the first African regulatory body to approve CAB-LA for HIV-PrEP. Furthermore, the World Health Organization's Guideline Development Group has conditionally recommended CAB-LA as an adjunctive preventive measure for those at substantial risk of HIV-1 infection.

Delivery device(s)

No delivery device

Scale-up and manufacturing prospects

Scale-up prospects

Compound is commercially manufactured by the innovator and three generic manufacturers have received a licence through the medicines patent pool to manufacture generic versions by 2026/2027.

Tentative equipment list for manufacturing

Conventional wet-bead milling (ball mill), depyrogenated glass vials.

Manufacturing

Cabotegravir is subject to a gamma-irradiation pre-sterilization step prior to a conventional wet-bead milling manufacturing procedure. The Cabotegravir milling process is initiated alongside pharmaceutical excipients (polyethylene glycol 3350, water for injection, polysorbate 20 and mannitol) for an overall 200nm drug particle size. Sterilized de-pyrogenated glass vials are used to store the finished drug nanosuspension, before an additional gamma irradiation (25kGy) step to ensure aseptic packaging conditions.

Specific analytical instrument required for characterization of formulation

PANalytical X’Pert PRO diffractometer equipped with a theta/theta coupled goniometer (or equivalent x-ray powder diffractor) to determine drug particle size, Mettler TGA/DSC 1 instrument for thermal analysis, HPLC to evaluate drug content, impurities and dissolution, HPLC UV-Vis Detector for drug identification.

Clinical trials

ECLAIR

Identifier

NCT02076178

Link

https://clinicaltrials.gov/study/NCT02076178

Phase

Phase II

Status

Completed

Sponsor

ViiV Healthcare

More details

Not provided

Purpose

Evaluate the safety, tolerability and acceptability of long acting injections of the HIV integrase inhibitor, GSK1265744, in HIV-uninfected men.

Interventions

Intervention 1

Drug: 744 (Cabotegravir) Tablet

Dosage: 30 mg

Intervention 2

Drug: 744 (Cabotegravir) LA Injection

Dosage: 800 mg (200 mg/mL)

Intervention 3

Drug: Placebo Tablet

Dosage: 0 mg

Intervention 4

Drug: Placebo Injection

Dosage: 0 mg

Countries

United States of America

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2014-03-27

Anticipated Date of Last Follow-up

2017-12-13

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2015-05-15

Actual Completion Date

2016-02-23

Studied populations

Age Cohort

- Adults
- Older Adults

Genders

- Cisgender male
- Transgender male

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

Yes

Comments about the studied populations

Inclusion Criteria: - Non-reactive HIV test at screening or enrollment. - Males 18 to 65 years old at the time of signing the informed consent. - At risk of acquiring HIV, defined as having at least one casual sex partner in the past 24 months. - Healthy as determined by a responsible and experienced physician, based on a medical evaluation including medical history, physical examination, laboratory tests and cardiac monitoring at the time of screening. - If participating in sexual activity with a

female of child-bearing potential, men must agree to use condoms. Female partner must use contraception. - Capable of giving written informed consent, which includes compliance with the requirements and restrictions listed in the consent form. - Willing to undergo all required study procedures.

Health status

Negative to : HIV, HBV, HCV
Considered at low risk of : HIV

Study type

Interventional (clinical trial)

Enrollment

127

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Double-blind masking

Masking description

Double (Participant, Investigator)

Frequency of administration

Other : "Three time points at 12 week intervals. "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

PrEP

Key results

Type of key results	Title	Website link
Article	Satisfaction and acceptability of cabotegravir long-acting injectable suspension for prevention of HIV: Patient perspectives from the ECLAIR trial	https://pubmed.ncbi.nlm.nih.gov/30445
Article	Safety and tolerability of long-acting cabotegravir injections in HIV-uninfected men (ECLAIR): a multicentre, double-blind, randomised, placebo-controlled, phase 2a trial	https://pubmed.ncbi.nlm.nih.gov/28546

HPTN 077

Identifier

NCT02178800

Link

https://clinicaltrials.gov/study/NCT02178800

Phase

Phase II

Status

Completed

Sponsor

National Institute of Allergy and Infectious Diseases

More details

Not provided

Purpose

Evaluate the safety, tolerability, and pharmacokinetics of an investigational, injectable HIV medicine (GSK1265744) in HIV-uninfected adults.

Interventions

Intervention 1

Drug: GSK1265744 Tablets

Dosage: 30 mg tablets, taken orally

Intervention 2

Drug: Injectable GSK1265744
Dosage: 800 mg injection, administered as two 400-mg intramuscular (IM) gluteal injections

Intervention 3
Drug: Placebo for GSK1265744 Tablets
Dosage: 0 mg Taken orally

Intervention 4
Drug: Injectable GSK1265744
Dosage: 600 mg injection, administered as one IM gluteal injection

Intervention 5
Drug: Injectable Placebo for GSK1265744
Dosage: Sodium Chloride for Injection USP, 0.9%; administered as two 400-mg IM gluteal injections or as one 600-mg IM gluteal injection

Countries

United States of America
Brazil
Malawi
South Africa

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date
Not provided

Actual Start Date
2015-02-01

Anticipated Date of Last Follow-up

2021-10-14

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2017-04-05

Actual Completion Date

2018-07-13

Studied populations

Age Cohort

- Adults
- Older Adults

Genders

- All

Accepts pregnant individuals

No

Accepts lactating individuals

No

Accepts healthy individuals

Yes

Comments about the studied populations

Men and women, 18 to 65 years old at the time of screening, who are willing to provide informed consent for the study. Participants are required to be in general good health, as confirmed by laboratory investigation, with no medical condition(s) that

would interfere with the conduct of the study.

Health status

Considered at low risk of : HIV
Negative to : HBV, HCV, HIV

Study type

Interventional (clinical trial)

Enrollment

199

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Quadruple-blind masking

Masking description

Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Frequency of administration

Other : "Injection of GSK1265744 three times at twelve-week intervals. "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

PrEP

Key results

Type of key results	Title	Website link
Article	Tail-phase safety, tolerability, and pharmacokinetics of long-acting injectable cabotegravir in HIV-uninfected adults: a secondary analysis of the HPTN 077 trial	https://pubmed.ncbi.nlm.nih.gov/32497
Article	Safety, tolerability, and pharmacokinetics of long-acting injectable cabotegravir in low-risk HIV-uninfected individuals: HPTN 077, a phase 2a randomized controlled trial	https://pubmed.ncbi.nlm.nih.gov/30408

HPTN 083

Identifier

NCT02720094

Link

https://clinicaltrials.gov/study/NCT02720094

Phase

Phase II/III

Status

Active, not recruiting

Sponsor

National Institute of Allergy and Infectious Diseases

More details

Not provided

Purpose

Evaluate the safety and efficacy of the injectable drug cabotegravir (CAB LA), for pre-exposure prophylaxis (PrEP) in HIV-uninfected cisgender men and transgender women who have sex with men.

Interventions

Intervention 1
Drug: Cabotegravir Oral Tablet
Dosage: 30 mg tablet

Intervention 2

Drug: TDF/FTC tablets

Dosage: 300 mg/200 mg fixed-dose combination tablets

Intervention 3

Drug: Placebo for TDF/FTC and cabotegravir tablets

Dosage: 0 mg

Intervention 4

Drug: CAB LA

Dosage: Administered as one 3 mL (600 mg) IM injection in the gluteal muscle at two time points 4 weeks apart and every 8 weeks thereafter

Intervention 5

Drug: Placebo for CAB LA

Dosage: Administered as one 3 mL IM injection in the gluteal muscle at two time points 4 weeks apart and every 8 weeks thereafter

Countries

United States of America

Argentina

Brazil

Peru

South Africa

Thailand

Viet Nam

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2016-12-01

Anticipated Date of Last Follow-up

2024-03-11

Estimated Primary Completion Date

Not provided

Estimated Completion Date

2024-07-01

Actual Primary Completion Date

2020-05-14

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adults
- Older Adults

Genders

- Cisgender male
- Transgender female

Accepts pregnant individuals

No

Accepts lactating individuals

No

Accepts healthy individuals

Yes

Comments about the studied populations

HIV negative cis-gender men and transgender women (18 years or older at the time of screening [assigned male at birth]) who have sex with men and at high risk of HIV infection.

Health status

Considered high risk to : HIV
Negative to : HIV, HCV, HBV

Study type

Interventional (clinical trial)

Enrollment

4570

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Quadruple-blind masking

Masking description

Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Frequency of administration

Monthly

Once every 2 months

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

PrEP

Key results

Type of key results	Title	Website link
Article	Cabotegravir for HIV Prevention in Cisgender Men and Transgender Women	https://pubmed.ncbi.nlm.nih.gov/34379

HPTN 084

Identifier

NCT03164564

Link

https://clinicaltrials.gov/study/NCT03164564

Phase

Phase III

Status

Active, not recruiting

Sponsor

National Institute of Allergy and Infectious Diseases

More details

Not provided

Purpose

Evaluate the safety and efficacy of CAB LA compared to daily oral tenofovir disoproxil fumarate/emtricitabine for PrEP in HIV-uninfected women.

Interventions

Intervention 1

Drug: Oral CAB

Dosage: 30 mg tablet

Intervention 2

Drug: Oral TDF/FTC
Dosage: 300 mg/200 mg fixed dose combination tablet

Intervention 3
Drug: Placebo for oral CAB, Drug: Placebo for CAB LA
Dosage: 0 mg

Intervention 4
Drug: Placebo for oral TDF/FTC
Dosage: 0 mg

Intervention 5
Drug: CAB LA
Dosage: 600 mg administered as one 3 mL (600 mg) intramuscular injection in the gluteal muscle

Countries

Botswana
Kenya
Malawi
South Africa
Eswatini
Uganda
Zimbabwe

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date
Not provided

Actual Start Date
2017-11-07

Anticipated Date of Last Follow-up

2023-03-21

Estimated Primary Completion Date

Not provided

Estimated Completion Date

2024-11-30

Actual Primary Completion Date

2020-11-05

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adults

Genders

- Cisgender female

Accepts pregnant individuals

No

Accepts lactating individuals

No

Accepts healthy individuals

Yes

Comments about the studied populations

Born female and 18-45 years of age at the time of screening. Must have documented evidence of surgical sterilization, OR documented evidence of no uterus (e.g., hysterectomy), OR must agree to use a reliable form of long acting contraception,

during the trial and for 52 weeks after stopping the long acting injectable, or 30 days after stopping oral study product

Health status

Negative to : HIV, HBV, HCV
Considered high risk to : HIV

Study type

Interventional (clinical trial)

Enrollment

3224

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Quadruple-blind masking

Masking description

Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Frequency of administration

Monthly
Once every 2 months

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

PrEP

Key results

Type of key results	Title	Website link
Article	Cabotegravir for the prevention of HIV-1 in women: results from HPTN 084, a phase 3, randomised clinical trial	https://pubmed.ncbi.nlm.nih.gov/35378

EBONI

Identifier

NCT05514509

Link

https://clinicaltrials.gov/study/NCT05514509

Phase

Marketed

Status

Recruiting

Sponsor

ViiV Healthcare

More details

Not provided

Purpose

Evaluate implementation strategies for the delivery of CAB for HIV PrEP across clinical settings for adult (≥18 Years) black cis-and transgender women without HIV infection living in the United States

Interventions

Intervention 1

Drug: APRETUDE

Intervention 2

Drug: Cabotegravir tablet

Countries

United States of America

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2022-10-28

Anticipated Date of Last Follow-up

2024-05-30

Estimated Primary Completion Date

2025-09-30

Estimated Completion Date

2025-09-30

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adults
- Older Adults

Genders

- Cisgender female
- Transgender female

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

Yes

Comments about the studied populations

Inclusion criteria: - Participant must be ≥18 years of age, at the time of signing the informed consent. - HIV negative at screening. Type of HIV-1 test is per standard of care. - No prior history of receiving oral CAB or CAB LA injections. - PrEP provider deems CAB PrEP use to be appropriate per the applicable CAB PrEP prescribing information prior to enrollment in the study. - Female at birth or self-identified Transgender Female. - Self-identified as African American/Black. - Capable of giving signed informed consent.

Health status

Negative to : HIV

Study type

Interventional (clinical trial)

Enrollment

250

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Open label

Masking description

None (Open Label)

Frequency of administration

Other

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

PrEP

Key results

Not provided

PILLAR

Identifier

NCT05374525

Link

https://clinicaltrials.gov/study/NCT05374525

Phase

Marketed

Status

Recruiting

Sponsor

ViiV Healthcare

More details

Not provided

Purpose

Evaluate implementation strategies for the delivery of cabotegravir PrEP for HIV uninfected MSM and transgender men ≥ 18 in the United States.

Interventions

Intervention 1

Drug: APRETUDE

Intervention 2

Drug: Cabotegravir Tablet (Oral Lead-In Period)

Countries

United States of America

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2022-05-18

Anticipated Date of Last Follow-up

2024-02-13

Estimated Primary Completion Date

2024-09-06

Estimated Completion Date

2024-09-06

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adults
- Older Adults

Genders

Cisgender male
- Transgender male

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

Yes

Comments about the studied populations

Not provided

Health status

Negative to : HIV

Study type

Interventional (clinical trial)

Enrollment

116

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Open label

Masking description

None (Open Label)

Frequency of administration

Other : "followed by the first two APRETUDE IM injections administered monthly and subsequent injections every two months thereafter. "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

PrEP

Key results

Not provided

ImPrEP

Identifier

NCT05515770

Link

https://clinicaltrials.gov/study/NCT05515770

Phase

Phase III

Status

Not yet recruiting

Sponsor

Evandro Chagas National Institute of Infectious Disease

More details

Not provided

Purpose

Assess the safety and effectiveness of open label CAB LA PrEP when offered at public health facilities to cisgender men and transgender or gender non-binary individuals who have sex with men.

Interventions

Intervention 1

Drug: Cabotegravir Injection (Apretude)

Countries

Brazil

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

2022-09-20

Actual Start Date

Not provided

Anticipated Date of Last Follow-up

2022-08-24

Estimated Primary Completion Date

2025-10-01

Estimated Completion Date

2026-02-01

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adults

Genders

- Cisgender male
- Transgender female

Transgender male
- Gender non-binary

Accepts pregnant individuals

No

Accepts lactating individuals

No

Accepts healthy individuals

Yes

Comments about the studied populations

Cisgender men, non-binary (assigned as male at birth), transgender women and transgender men who are seeking a PrEP study clinic and age 18-30 years. Study participants must report having anal sex in the last six months with a person assigned male gender at birth.

Health status

Negative to : HIV

Study type

Interventional (clinical trial)

Enrollment

1200

Allocation

Not provided

Intervention model

Single group assignment

Intervention model description

Methods include qualitative (focus group discussion and in-depth interviews) and quantitative (service statistics, laboratory tests, surveys) approaches. The incidence of HIV in the CAB LA study cohort will be evaluated against a similar cohort receiving oral PrEP. Interrupted time series analysis will be utilised to assess the effectiveness of the mHealth intervention.

Masking

Open label

Masking description

None (Open Label)

Frequency of administration

Once every 2 months

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

PrEP

Key results

Not provided

SEARCH SAPPHIRE DCP Extension

Identifier

NCT05549726

Link

https://clinicaltrials.gov/study/NCT05549726

Phase

Marketed

Status

Active, not recruiting

Sponsor

University of California, San Francisco

More details

Not provided

Purpose

Determine whether adding the option of CAB-LA as HIV PrEP increases prevention coverage compared to the standard-of-care in three ongoing randomized trials of dynamic choice in rural Uganda and Kenya.

Interventions

Intervention 1

Drug: Cabotegravir Injectable Suspension

Dosage: 600 mg/3 mL (200 mg/mL)

Intervention 2

Other: Dynamic Choice Delivery Model

Intervention 3

Other: Standard of Care

Countries

Kenya

Uganda

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2023-01-02

Anticipated Date of Last Follow-up

2024-02-23

Estimated Primary Completion Date

Not provided

Estimated Completion Date

2025-01-01

Actual Primary Completion Date

2023-12-18

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adolescents
- Adults
- Older Adults

Genders

- All

Accepts pregnant individuals

No

Accepts lactating individuals

No

Accepts healthy individuals

Yes

Comments about the studied populations

Participants must be enrolled in a SEARCH Sapphire Dynamic prevention study (NCT04810650).

Health status

Negative to : HIV, HBV
Considered at low risk of : HIV

Study type

Interventional (clinical trial)

Enrollment

984

Allocation

Non-randomized

Intervention model

Parallel Assignment

Intervention model description

CAB-LA will be offered to participants that are initially assigned to the Dynamic Choice Prevention delivery model.

Masking

Open label

Masking description

None (Open Label)

Frequency of administration

Other

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

PrEP

Key results

Not provided

NCT02478463

Identifier

NCT02478463

Link

https://clinicaltrials.gov/study/NCT02478463

Phase

Phase I

Status

Completed

Sponsor

ViiV Healthcare

More details

Not provided

Purpose

Determine the PK concentrations of CAB following LA administration in relevant tissues and fluids of healthy men and women following a single 600 mg IM dose.

Interventions

Intervention 1

Drug: Cabotegravir tablet

Dosage: 30 mg

Intervention 2

Drug: Cabotegravir injection

Dosage: 3 mL (200 mg/mL)

Countries

United States of America

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2017-02-27

Anticipated Date of Last Follow-up

2020-06-02

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2019-07-25

Actual Completion Date

2019-07-25

Studied populations

Age Cohort

- Adults

Genders

- All

Accepts pregnant individuals

No

Accepts lactating individuals

No

Accepts healthy individuals

Yes

Comments about the studied populations

Inclusion Criteria: - Between 18 and 55 years of age inclusive, at the time of signing the informed consent. - Healthy as determined by the investigator or medically qualified designee based on a medical evaluation including medical history, physical examination, laboratory tests and cardiac monitoring. - Body weight >= 40 kilogram (kg) and body mass index (BMI) within the range 18.5 to 35 kg /meter square (inclusive). - Male or female. - Capable of giving signed informed consent, which includes compliance with the requirements and restrictions listed in the consent form and in this protocol. - All subjects participating in the study must be counselled on safe sexual practices including the use of effective barrier methods to minimize risk of HIV transmission.

Health status

Negative to : HIV, HBV, HCV

Study type

Interventional (clinical trial)

Enrollment

19

Allocation

Not provided

Intervention model

Single group assignment

Intervention model description

Not provided

Masking

Open label

Masking description

None (Open Label)

Frequency of administration

Other : "Single dose "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

PrEP

Key results

Not provided

NCT03422172

Identifier

NCT03422172

Link

https://clinicaltrials.gov/study/NCT03422172

Phase

Phase I

Status

Completed

Sponsor

ViiV Healthcare

More details

Not provided

Purpose

Evaluate the PK, safety, tolerability, and acceptability of CAB LA in adult HIV uninfected Chinese male subjects at low risk for HIV acquisition.

Interventions

Intervention 1

Drug: Oral CAB

Dosage: 30 mg

Intervention 2

Drug: CAB LA Injection

Dosage: 600 mg (200 mg/mL)

Countries

China

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2018-04-10

Anticipated Date of Last Follow-up

2021-05-12

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2020-04-20

Actual Completion Date

2020-04-20

Studied populations

Age Cohort

- Adults

Older Adults

Genders

- Cisgender male

Accepts pregnant individuals

No

Accepts lactating individuals

No

Accepts healthy individuals

Yes

Comments about the studied populations

Inclusion Criteria: - Subjects must be 18 to 65 years of age inclusive, at the time of signing the informed consent. - Subjects are male at birth. - Subjects who have non-reactive point of care (POC) HIV test and undetectable HIV-1 ribose nucleic acid (RNA) at screening. - At risk of acquiring HIV, defined as having at least one casual male or female sex partner in the past 24 months. - Healthy as determined by a responsible and experienced physician, based on a medical evaluation including medical history, physical examination, laboratory tests and cardiac monitoring at the time of screening. - Capable of giving written informed consent. - Agree to appropriate use of contraceptive measures during heterosexual intercourse. - Willing to undergo all required study procedures.

Health status

Considered at low risk of : HIV
Negative to : HIV, HBV, HCV

Study type

Interventional (clinical trial)

Enrollment

48

Allocation

Not provided

Intervention model

Single group assignment

Intervention model description

Eligible subjects will receive oral doses of CAB for 4 weeks followed by IM dosing with CAB LA at Week 5, Week 9, Week 17, Week 25 and Week 33.

Masking

Open label

Masking description

None (Open Label)

Frequency of administration

Other : "Week 5, Week 9, Week 17, Week 25 and Week 33. "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

PrEP

Key results

Type of key results	Title	Website link
Article	Safety, Tolerability, Pharmacokinetics, and Acceptability of Oral and Long-Acting Cabotegravir in HIV-Negative Chinese Men	https://doi.org/10.1128/aac.02057-21

PALISADE

Identifier

NCT06134362

Link

https://clinicaltrials.gov/study/NCT06134362

Phase

Phase III

Status

Not yet recruiting

Sponsor

ViiV Healthcare

More details

Not provided

Purpose

Long-term follow-up and evaluation of CAB LA for participants in the HPTN 083 and HPTN 084 CAB PrEP studies who are at risk of HIV acquisition.

Interventions

Intervention 1

Drug: CAB LA

Dosage: 600 mg

Countries

Argentina

Botswana

Brazil

Kenya

Malawi

Peru

South Africa

Thailand

Uganda

Viet Nam

Zimbabwe

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

2024-04-01

Actual Start Date

Not provided

Anticipated Date of Last Follow-up

2024-01-29

Estimated Primary Completion Date

2027-06-24

Estimated Completion Date

2027-06-24

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Children
- Adolescents
- Adults
- Older Adults

Genders

- All

Accepts pregnant individuals

Yes

Accepts lactating individuals

Unspecified

Accepts healthy individuals

Yes

Comments about the studied populations

Participants must be currently enrolled and ongoing in one of the following studies: (1) HPTN 083 (2) HPTN 084 (3) HPTN 083 and HPTN 084 adolescent and pregnancy sub-studies Participants who have permanently withdrawn from prior CAB PrEP studies cannot enroll into this study.

Health status

Negative to : HIV, HBV
Considered high risk to : HIV

Study type

Interventional (clinical trial)

Enrollment

3500

Allocation

Not provided

Intervention model

Single group assignment

Intervention model description

Not provided

Masking

Open label

Masking description

None (Open Label)

Frequency of administration

Once every 2 months

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

PrEP

Key results

Not provided

TSHIRELETSO

Identifier

NCT05986084

Link

https://clinicaltrials.gov/study/NCT05986084

Phase

Marketed

Status

Recruiting

Sponsor

Beth Israel Deaconess Medical Center

More details

Not provided

Purpose

aluate whether using long-acting cabotegravir (CAB-LA) for HIV prevention (PrEP) is acceptable, feasible and safe in postpartum people who are breastfeeding.

Interventions

Intervention 1

Drug: Cabotegravir Injection [Apretude]

Dosage: 600 mg

Countries

United States of America

Botswana

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2023-11-30

Anticipated Date of Last Follow-up

2024-07-12

Estimated Primary Completion Date

2027-08-01

Estimated Completion Date

2027-08-31

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adults
- Older Adults

Genders

Cisgender female

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Yes

Accepts healthy individuals

No

Comments about the studied populations

Participants are postpartum (< 14 days after delivery) mothers who are aged 18-30 with less than a total of three prior pregnancies. Participants should plan to stay and receive postpartum and paediatric care in the Gaborone or Molepolole region of Botswana for at least 24 months.

Health status

Considered at low risk of : HIV
Negative to : HIV, TB

Study type

Interventional (clinical trial)

Enrollment

500

Allocation

Not provided

Intervention model

Single group assignment

Intervention model description

Not provided

Masking

Open label

Masking description

None (Open Label)

Frequency of administration

Once every 2 months

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

PrEP

Key results

Not provided

AXIS

Identifier

NCT06138600

Link

https://clinicaltrials.gov/study/NCT06138600

Phase

Phase III

Status

Completed

Sponsor

University of Witwatersrand, South Africa

More details

This is a mixed methods study employing a convergence model triangulation design. Participants in the study will be sexually active young adults starting Pre-exposure Prophylaxis at private pharmacies, who will be offered either Cabotegravir Long-Acting Injectable, oral Pre-exposure Prophylaxis (TDF/FTC\[3TC\]), or Pre-exposure Prophylaxis deferment at each of their regular visits, with the option to switch between options for up to 15 months, with a final exit interview following the transition to standard-of-care. The number of study visits will vary, depending on participant Pre-exposure Prophylaxis choices. Those choosing oral Pre-exposure Prophylaxis will be seen 3 monthly from V2 onwards, but those choosing Cabotegravir Long-Acting Injectable will be seen 2 monthly from V2. A maximum

Purpose

Acceptability and Feasibility of Injectable Cabotegravir Pre-exposure Prophylaxis (PrEP) Versus Oral PrEP in Routine Care up to 15 Months in Private Pharmacies in South Africa

Interventions

Intervention 1

Cabotegravir Injection [Apretude]

Intervention 2

Tenofovir disoproxil fumarate / emtricitabine (or lamivudine)

Countries

South Africa

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2023-11-01

Anticipated Date of Last Follow-up

2024-06-19

Estimated Primary Completion Date

2025-10-31

Estimated Completion Date

2026-01-31

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adults

Genders

- All

Accepts pregnant individuals

No

Accepts lactating individuals

No

Accepts healthy individuals

Yes

Comments about the studied populations

Inclusion criteria: - Each participant must meet all of the following criteria to be enrolled in this study: 1. Adult male or female (≥18 and ≤ 35 years old) 2. Is self-reported sexually active 3. HIV negative at the time of study enrolment (as determined by a rapid blood test for HIV 1) 4. Body weight ≥ 35 kilograms. 5. Creatinine clearance ≥ 60 mL/min. 6. Willingness to sign informed consent.

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

200

Allocation

Non-randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Once every 2 months

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

PrEP

Key results

Not provided

PEACH

Identifier

NCT05072093

Link

https://clinicaltrials.gov/study/NCT05072093

Phase

Marketed

Status

Active, not recruiting

Sponsor

Emory University

More details

The study is a prospective cohort of young MSM who are followed for 2 years either in-person at the PRISM Health Research Clinic and/or virtually with telehealth study visits. Follow-up visits occur as frequently as every 3 months, or as appropriate to clinical needs of HIV PrEP or STI PEP. The investigators will enroll men who may decide to start or stop PrEP, change from daily oral PrEP to on-demand oral PrEP or from on-demand oral PrEP to daily PrEP, to start or stop STI PEP at any point in the study period, or injectable PrEP as an alternative to daily oral PrEP or on-demand oral PrEP. All men will be provided with the study's mobile smart phone app to support early identification of risks for PrEP discontinuation, to provide information about STI PEP and document usage patterns of on-

Purpose

Parrying the Pitfalls of PrEP: Project PEACH

Interventions

Intervention 1

on-demand oral PrEP

Intervention 2

STI PEP

Intervention 3

Injectable PrEP

Countries

United States of America

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2021-11-20

Anticipated Date of Last Follow-up

2024-06-11

Estimated Primary Completion Date

2025-02-01

Estimated Completion Date

2025-02-01

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adults

Genders

- Male

Accepts pregnant individuals

No

Accepts lactating individuals

No

Accepts healthy individuals

Yes

Comments about the studied populations

Inclusion Criteria: * Male at birth * Self-identify as Cisgender Male * Ages 18-45 years * ≥1 male anal sex partner in the 12 months before the baseline interview * Live in the Atlanta MSA * Owns cell phone with data service * Willing to download a health-related app to their cell phone as part of the research study * Able to provide ≥ 2 means of contact * Not currently enrolled in another HIV prevention clinical trial * Confirmed HIV-negative at baseline visit Exclusion Criteria: * Female at birth * Do not self-identify as Cisgender Male * Individuals \< 18 years of age or \> 45 years of age * HIV positive status * No male anal sex partner in the 12 months before the baseline interview * Does not own mobile phone with data service * Not willing to download a health-related app to their

Health status

Negative to : HIV

Study type

Interventional (clinical trial)

Enrollment

240

Allocation

Not provided

Intervention model

Single group assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Once every 2 months

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

PrEP

Key results

Not provided

MOBILEMEN

Identifier

NCT06133686

Link

https://clinicaltrials.gov/study/NCT06133686

Phase

Phase III

Status

Not yet recruiting

Sponsor

MRC/UVRI and LSHTM Uganda Research Unit

More details

Title: Implementing oral (event-driven and daily) and long-acting Pre-exposure prophylaxis (PrEP) in mobile men in Sub-Saharan Africa Design: A mixed method, multi-setting, multi-country, phase 3b, open-label, hybrid type 2 implementation and effectiveness randomized controlled trial (RCT). The trial will be carried out in 400 HIV negative men aged 18+ years in South Africa and Uganda. Men will be randomized 1:1 to either Group A: oral Tenofovir disoproxil fumarate/emtricitabine (TDF-FTC) PrEP (event-driven or daily) or Group B: Long-acting injectable cabotegravir (CAB-LA) over 9-months. After 9-months participants from both groups will be offered choice of PrEP (oral TDF-FTC or CAB-LA) for a further 9-months, with the ability to change choice as required. Various strategies to support Pr

Purpose

Implementing Oral (Event-driven and Daily) and Long-acting Pre-Exposure Prophylaxis in Mobile Men in Sub-Saharan Africa

Interventions

Intervention 1

Tenofovir disoproxil fumarate/emtricitabine (TDF-FTC), cabotegravir (CAB-LA)

Intervention 2

Cabotegravir (CAB-LA), Tenofovir disoproxil fumarate/emtricitabine (TDF-FTC)

Countries

South Africa
Uganda

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

2024-04-01

Actual Start Date

Not provided

Anticipated Date of Last Follow-up

2023-11-13

Estimated Primary Completion Date

2025-12-31

Estimated Completion Date

2027-04-01

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adults

Genders

- Male

Accepts pregnant individuals

No

Accepts lactating individuals

No

Accepts healthy individuals

Yes

Comments about the studied populations

Inclusion Criteria: 1. Able and willing to provide informed consent 2. Aged 18 years and above on the day of screening 3. Willing to have a HIV test and receive the test results 4. Male at birth 5. In the past 6-months has travelled for work or to find work and spent at least one night away from home for work related purposes. 6. Available for follow up for the duration of the study Exclusion Criteria: 1. Known HIV infection 2. Confirmed HIV-positive test result, indeterminate HIV test result, and/or signs and symptoms of an acute HIV infection 3. Body weight less than 35Kg at baseline 4. Allergy to any of the study products 5. Medical, social or other condition that, in the opinion of the site investigator, would interfere with the conduct of the study or safety of the participant (e.g

Health status

Negative to : HIV

Study type

Interventional (clinical trial)

Enrollment

400

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Once every 2 months

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

PrEP

Key results

Not provided

PathToScale

Identifier

NCT06319105

Link

https://clinicaltrials.gov/study/NCT06319105

Phase

Marketed

Status

Recruiting

Sponsor

Georgetown University

More details

The purpose of this study is to evaluate the implementation and clinical outcomes of expanded pre-exposure prophylaxis delivery modalities and service delivery points offering long-acting injectable cabotegravir and oral pre-exposure prophylaxis to high-priority groups through diverse delivery channels.

Purpose

PathToScale: An Implementation Evaluation

Interventions

Intervention 1

Standard intervention: Offer PrEP choice

Intervention 2

cabotegravir LA

Intervention 3

oral PreP

Intervention 4

any other PrEP method

Countries

Malawi

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2024-03-26

Anticipated Date of Last Follow-up

2024-03-28

Estimated Primary Completion Date

2026-04-01

Estimated Completion Date

2026-04-01

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

Unspecified

Genders

Unspecified

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

Unspecified

Comments about the studied populations

Not provided

Health status

Not provided

Study type

Observational studies (incl. patient registries)

Enrollment

9900

Allocation

Non-randomized

Intervention model

Single group assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Once every 2 months

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

PrEP

Key results

Not provided

IDCaPP

Identifier

NCT05867212

Link

https://clinicaltrials.gov/study/NCT05867212

Phase

Marketed

Status

Active, not recruiting

Sponsor

Kelley-Ross & Associates, Inc.

More details

The goal of this demonstration project or observational study is to evaluate the feasibility and acceptability of a pharmacist-managed cabotegravir long acting injectable for PrEP program in a community pharmacy setting. The main question it aims to answer are: * Is the program feasible and acceptable at the end of 1 year of operations? * What are the facilitators and barriers of the program? Participants who want to start the FDA approved cabotegravir long acting injectable medication for PrEP will have the option participating in surveys and a review of their electronic health records. Medication will be administered based on FDA approved labeling guidelines and their PrEP care will be part of standard of care per CDC. Pharmacists who want to provide the service to their patients will

Purpose

Implementation and Delivery of Cabotegravir Long Acting Injection for PrEP in a Community Pharmacy Setting.

Interventions

Intervention 1

Cabotegravir Injection [Apretude]

Countries

United States of America

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

2023-06-01

Actual Start Date

Not provided

Anticipated Date of Last Follow-up

2023-05-16

Estimated Primary Completion Date

2025-11-30

Estimated Completion Date

2025-11-30

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adults

Genders

- All

Accepts pregnant individuals

Yes

Accepts lactating individuals

Yes

Accepts healthy individuals

Yes

Comments about the studied populations

Not provided

Health status

Negative to : HIV

Study type

Observational studies (incl. patient registries)

Enrollment

50

Allocation

Non-randomized

Intervention model

Single group assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Once every 2 months

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

PrEP

Key results

Not provided

HIPCY

Identifier

NCT06474364

Link

https://clinicaltrials.gov/study/NCT06474364

Phase

Marketed

Status

Active, not recruiting

Sponsor

MU-JHU CARE

More details

Several studies show that Adolescents and Young Adults (AYA) have poor outcomes along the entire Human Immunodeficiency Virus (HIV) prevention and care cascades compared to adults. The investigators propose to evaluate novel evidence-based HIV prevention and care interventions (including Cabotegravir LongActing (CABLA) to determine implementation outcomes among AYA who are at particularly high risk for HIV acquisition and poor viral suppression in five geographically distinct research performance sites in Uganda. The results will provide important evidence to inform Uganda and other regional countries' policy on integrated HIV prevention, care and treatment for AYA at high risk for HIV and Sexually Transmitted Infections (STIs) in order to reach the UNAIDS 95-95-95 targets and HIV epidemic

Purpose

HIV Prevention and Care Interventions for Youth in Uganda

Interventions

Intervention 1

Long-acting Cabotegravir injection

Intervention 2

SEARCH-YOUTH

Countries

Uganda

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

2024-07-15

Actual Start Date

Not provided

Anticipated Date of Last Follow-up

2024-06-19

Estimated Primary Completion Date

2028-08-31

Estimated Completion Date

2028-08-31

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adolescents
- Adults

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

Yes

Comments about the studied populations

Inclusion Criteria: Adolescents and young adults with increased likelihood of HIV acquisition * AYA 15 to 24 years of age * Classified as high risk using our screening tool. * Documented HIV un-infected as per the national HIV testing algorithm. * Willing to use PrEP * Willing to provide written informed consent. * No plans to relocate permanently in the next 6 months * No suspicion of acute HIV infection: * Hepatitis B virus surface antigen (HBsAg)-negative and accepts HB vaccination * Having no medical or social condition that, in the opinion of the study investigator, would interfere with the conduct of the study or interpretation of study results. * HIV-uninfected, based on HIV test results obtained at screening and enrolment visit and just prior to randomization. All HIV test res

Health status

Negative to : HIV

Study type

Interventional (clinical trial)

Enrollment

600

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Once every 2 months

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

PrEP

Key results

Not provided

CATALYST

Identifier

NCT05937698

Link

https://clinicaltrials.gov/study/NCT05937698

Phase

Marketed

Status

Recruiting

Sponsor

FHI 360

More details

The CATALYST study is an implementation study that will characterize and assess the implementation of an enhanced service delivery package providing informed choice of pre-exposure prophylaxis (PrEP) products among women at PEPFAR sites in Kenya, Lesotho, South Africa, Uganda, and Zimbabwe.

Purpose

The CATALYST Study

Interventions

Not provided

Countries

Lesotho

Kenya

Uganda

Zimbabwe

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2023-05-30

Anticipated Date of Last Follow-up

2024-07-29

Estimated Primary Completion Date

2025-06-30

Estimated Completion Date

2025-06-30

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

Unspecified

Genders

Unspecified

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

Unspecified

Comments about the studied populations

Not provided

Health status

Not provided

Study type

Observational studies (incl. patient registries)

Enrollment

11256

Allocation

Non-randomized

Intervention model

Single group assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Monthly

Once every 2 months

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

PrEP

Key results

Not provided

LAPIS

Identifier

NCT06250504

Link

https://clinicaltrials.gov/study/NCT06250504

Phase

Phase III

Status

Recruiting

Sponsor

Africa Health Research Institute

More details

The goal of this hybrid (1a) Cluster Randomised Controlled Trial phase 3B trial is to evaluate the effectiveness and implementation of offering a choice of HIV Pre-Exposure Products (PrEP) through community-based sexual and reproductive health services, on PrEP uptake and retention, and population prevalence of sexually transmissible HIV amongst adolescents and young adults living in rural South Africa. Researchers will compare adding the choice of long-acting PrEP, i.e. two monthly injectable cabotegravir (CAB LA) or dapiravine vaginal ring and HIV post exposure prophylaxis packs to daily oral PrEP integrated with community-based SRH in the 20 intervention clusters with standard of care (SoC), daily oral PrEP integrated with community-based SRH in the 20 control clusters, on uptake and r

Purpose

Long-Acting HIV Pre-Exposure Prophylaxis Integrated With Sexual and Reproductive Health - cRCT

Interventions

Intervention 1

APRETUDE (cabotegravir) 600 mg\3 mL

Intervention 2

DAPIRING (Dapivirine) 25mg Vaginal Ring

Intervention 3

tenofovir disoproxil and emtricitabine

Intervention 4

Tenofovir Disoproxil, Lamuvidine and Dolutegravir

Countries

South Africa

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2024-02-27

Anticipated Date of Last Follow-up

2024-04-16

Estimated Primary Completion Date

2025-07-01

Estimated Completion Date

2026-03-01

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Children
- Adults

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

Yes

Comments about the studied populations

Inclusion Criteria: All young men and women aged 15-30 who are residing in the 40 administrative clusters in the study district and attend any integrated SRH/HIV service Documented HIV negative test Suitable for PrEP and/or already on PrEP Weight \> 35 kg Understand the required dosing schedule and HIV testing. Aware that details can be shared with a peer navigator to support their follow-up If pregnant or breast feeding and/or planning to become pregnant participant can be offered CAB LA, if risk of acquiring HIV out weighs unknown risk of CAB LA, but must understand that safety in

pregnancy or breast feeding for CAB LA has not been established and oral daily PrEP is a safe alternative. Exclusion Criteria: History or presence of allergy to the study drugs or their components Inv

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

2000

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Double-blind masking

Masking description

Not provided

Frequency of administration

Once every 2 months

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

PrEP

Key results

Not provided

TIARAS-CAB-WWID

Identifier

NCT05799339

Link

https://clinicaltrials.gov/study/NCT05799339

Phase

Marketed

Status

Recruiting

Sponsor

Alexis Roth

More details

The goal of this study is to elicit information crucial for designing strategies to support engagement in cabotegravir, a long-acting injectable form of pre-exposure prophylaxis (PrEP) to reduce HIV risk among women who inject drugs (WWID), a population with high unmet need that has been understudied in all phases of PrEP research. The main questions this study aims to answer are: 1. How do WWID perceive long-acting injectable cabotegravir (CAB-LA) as a HIV prevention tool? 2. If and how their decisions to initiate CAB-LA as PrEP are informed by their experiences with other long-acting medications, experience with daily oral medications, and their personal circumstance (e.g., like housing or addition severity)? 3. Do PrEP outcomes (e.g., adherence) and engagement in care over time differ

Purpose

Optimizing CAB-LA as PrEP for Women Who Inject Drugs

Interventions

Not provided

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2022-01-13

Anticipated Date of Last Follow-up

2024-03-01

Estimated Primary Completion Date

2024-12-01

Estimated Completion Date

2024-12-01

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adults

Genders

- Female

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

Yes

Comments about the studied populations

Women who inject drugs

Health status

Negative to : HIV

Study type

Observational studies (incl. patient registries)

Enrollment

144

Allocation

Non-randomized

Intervention model

Single group assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Once every 2 months

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

PrEP

Key results

Not provided

AXIS

Identifier

NCT06138600

Link

https://clinicaltrials.gov/study/NCT06138600

Phase

Phase III

Status

Active, not recruiting

Sponsor

University of Witwatersrand, South Africa

More details

This is a mixed methods study employing a convergence model triangulation design. Participants in the study will be sexually active young adults starting Pre-exposure Prophylaxis at private pharmacies, who will be offered either Cabotegravir Long-Acting Injectable, oral Pre-exposure Prophylaxis (TDF/FTC\[3TC\]), or Pre-exposure Prophylaxis deferment at each of their regular visits, with the option to switch between options for up to 15 months, with a final exit interview following the transition to standard-of-care. The number of study visits will vary, depending on participant Pre-exposure Prophylaxis choices. Those choosing oral Pre-exposure Prophylaxis will be seen 3 monthly from V2 onwards, but those choosing Cabotegravir Long-Acting Injectable will be seen 2 monthly from V2. A maximum

Purpose

Acceptability and Feasibility of Injectable Cabotegravir Pre-exposure Prophylaxis (PrEP) Versus Oral PrEP in Routine Care up to 15 Months in Private Pharmacies in South Africa

Interventions

Intervention 1

Cabotegravir Injection [Apretude]

Intervention 2

Tenofovir disoproxil fumarate / emtricitabine (or lamivudine)

Countries

South Africa

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2023-11-01

Anticipated Date of Last Follow-up

2024-06-19

Estimated Primary Completion Date

2025-10-31

Estimated Completion Date

2026-01-31

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adults

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

Yes

Comments about the studied populations

Inclusion Criteria: - Each participant must meet all of the following criteria to be enrolled in this study: 1. Adult male or female (≥18 and ≤ 35 years old) 2. Is self-reported sexually active 3. HIV negative at the time of study enrolment (as determined by a rapid blood test for HIV 1) 4. Body weight ≥ 35 kilograms. 5. Creatinine clearance ≥ 60 mL/min. 6. Willingness to sign informed consent. Exclusion Criteria: - Participants meeting the following criteria will be excluded from participating in the study: 1. Symptoms of HIV seroconversion (see Table 1). 2. Pregnant (participant must have a negative beta human chorionic gonadotrophin (b-hCG) urine test at screening) or lactating women, or women intending to become pregnant or breastfeed during the study. 3. Is in good health, with

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

200

Allocation

Not provided

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Once every 2 months

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

PrEP

Key results

Not provided

223616

Identifier

NCT06970223

Link

https://clinicaltrials.gov/study/NCT06970223

Phase

Phase I

Status

Recruiting

Sponsor

ViiV Healthcare

More details

This study will evaluate the tolerability and acceptability of injection site reactions (ISRs) of two long-acting (LA) injectables. Additional characteristics of the ISRs will be investigated and described as well as safety outcomes.

Purpose

A Study to Investigate if Long Acting Cabotegravir (CAB) and Lenacapavir (LEN) Injections Are Tolerable and Acceptable When Administered to Healthy Adults Without HIV

Interventions

Not provided

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2025-04-22

Anticipated Date of Last Follow-up

2025-05-05

Estimated Primary Completion Date

2025-07-30

Estimated Completion Date

2026-07-07

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adults
- Older Adults

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

Yes

Comments about the studied populations

Inclusion Criteria: Participants are eligible to be included in the study only if all the following criteria apply: 1. At the time of obtaining informed consent, 18 years of age. 2. Body weight 50 kg and BMI within the range 18 to 32 kg/m2 (inclusive). 3. Participants who are overtly healthy as determined by medical evaluation by a responsible and experienced physician, including medical history, physical examination, laboratory tests and cardiac monitoring. 4. A participant with a significant clinical abnormality or laboratory parameter(s) which is/are not specifically listed in the inclusion or exclusion criteria, outside the reference range for the population being studied may be included if the investigator determines and documents that the finding is unlikely to introduce additional

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

60

Allocation

Randomized

Intervention model

Cross-over assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Not provided

Studied LA-formulation(s)

Not provided

Studied route(s) of administration

Not provided

Use case

Not provided

Key results

Not provided

Excipients

Proprietary excipients used

No proprietary excipient used

Novel excipients or existing excipients at a concentration above Inactive Ingredients Database (IID) for the specified route of administration

No novel excipient or existing excipient used

Residual solvents used

No residual solvent used

Patent info

Compound patent families

Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Cabotegravir crystalline forms Expiry date: 2038-01-25 A crystalline form and pharmaceutical compositions comprising it	WO2018149608	Polymorphs	Sandoz Ag	Yes	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted	Mexico	Australia, United Kingdom, France, Germany, United States of America
Filed	China	Canada
Not in force	World Intellectual Property Organization (WIPO), Morocco, Albania, Serbia, Bosnia and Herzegovina, Montenegro, Türkiye, Moldova, Republic of, North Macedonia, Tunisia	World Intellectual Property Organization (WIPO), Liechtenstein, Italy, Norway, Malta, Denmark, Belgium, Greece, Netherlands, Hungary, Croatia, Switzerland, Spain, San Marino, Slovenia, Austria, Romania, Iceland, Cyprus, Finland, Bulgaria, Slovakia, Poland, Latvia, Ireland, Estonia, Luxembourg, Portugal, Czechia, Lithuania, Monaco, Sweden, Russian Federation, United States of America

MPP Licence(s)

MPP Licence on Cabotegravir (tablet form and/or long-acting injectable form) for HIV pre-exposure prophylaxis (PrEP)

https://medicinespatentpool.org/licence-post/cabotegravir-long-acting-la-for-hiv-pre-exposure-prophylaxis-prep

Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Cabotegravir long-acting parenteral compositions Expiry date: 2031-09-15 The present invention relates to pharmaceutical compositions of cabotegravir useful in the treatment or prevention of Human Immunodeficiency Virus (HIV) infections.	WO2012037320	Composition	Glaxosmithkline Llc, Mundhra, Deepak B, Pan, Rennan, Viiv Healthcare Company	Yes	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted	Brazil, China, Turkmenistan, Belarus, Tajikistan, Kazakhstan, Azerbaijan, Kyrgyzstan, Armenia, Moldova, Republic of, Türkiye, North Macedonia, Albania, Bosnia and Herzegovina, Montenegro, Serbia, Mexico, Ukraine, South Africa, India	Australia, Canada, Chile, Russian Federation, Belgium, Germany, France, Luxembourg, Netherlands, Switzerland, United Kingdom, Sweden, Italy, Austria, Liechtenstein, Greece, Spain, Denmark, Monaco, Portugal, Ireland, Finland, Cyprus, Bulgaria, Czechia, Estonia, Slovakia, Hungary, Poland, Iceland, Malta, Norway, San Marino, Croatia, Romania, Latvia, Lithuania, Slovenia, Israel, Japan, Korea, Republic of, Taiwan, Province of China, United States of America
Filed		United States of America
Not in force	World Intellectual Property Organization (WIPO)	World Intellectual Property Organization (WIPO), United States of America

MPP Licence(s)

MPP Licence on Cabotegravir (tablet form and/or long-acting injectable form) for HIV pre-exposure prophylaxis (PrEP)

https://medicinespatentpool.org/licence-post/cabotegravir-long-acting-la-for-hiv-pre-

exposure-prophylaxis-prep

Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Cabotegravir processes and intermediates Expiry date: 2031-03-22 Relates to the preparation of carbamoylpyridone derivatives and intermediates which are useful as HIV integrase inhibitors.	WO2011119566	Intermediate(s), Process	Glaxosmithkline Llc	Yes	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted	China, Albania, Serbia, Bosnia and Herzegovina, Montenegro, Türkiye, North Macedonia, India	Liechtenstein, Italy, Norway, Malta, Denmark, Belgium, United Kingdom, Greece, Netherlands, Hungary, Croatia, Switzerland, Spain, San Marino, Slovenia, Austria, Romania, Iceland, Cyprus, Finland, France, Bulgaria, Slovakia, Poland, Latvia, Ireland, Estonia, Germany, Luxembourg, Portugal, Czechia, Lithuania, Monaco, Sweden, Japan, Korea, Republic of, United States of America
Filed		San Marino, Singapore, Taiwan, Province of China
Not in force	World Intellectual Property Organization (WIPO)	World Intellectual Property Organization (WIPO)

MPP Licence(s)

MPP Licence on Cabotegravir (tablet form and/or long-acting injectable form) for HIV pre-exposure prophylaxis (PrEP)

https://medicinespatentpool.org/licence-post/cabotegravir-long-acting-la-for-hiv-pre-exposure-prophylaxis-prep

Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Dolutegravir and Cabotegravir compounds Expiry date: 2026-04-28 The present invention is to provide a novel compound (I), having the anti-virus activity, particularly the HIV integrase inhibitory activity, and a drug containing the same, particularly an anti-HIV drug, as well as a process and an intermediate thereof. Compound (I) wherein Z<1> is NR<4>; R<1> is hydrogen or lower alkyl; X is a single bond, a hetero atom group selected from O, S, SO, SO2 and NH, or lower alkylene or lower alkenylene in which the hetero atom group may intervene; R<2> is optionally substituted aryl; R<3> is hydrogen, a halogen, hydroxy, optionally substituted lower alkyl etc; and R<4> and Z<2> part taken together forms a ring, to form a polycyclic compound, including e.g., a tricyclic or tetracyclic compound.	WO2006116764	Compound	Glaxosmithkline Llc	Yes	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income

Granted	Brazil, China, Morocco, Mexico, Philippines, Ukraine, Viet Nam, South Africa, Türkiye, Armenia, Azerbaijan, Belarus, Kyrgyzstan, Kazakhstan, Moldova, Republic of, Tajikistan, Turkmenistan, Nigeria, Colombia, Indonesia, Malaysia, Algeria	United States of America, Australia, Canada, Cyprus, Hong Kong, Israel, Japan, Korea, Republic of, Luxembourg, Norway, New Zealand, Taiwan, Province of China, Austria, Belgium, Bulgaria, Switzerland, Czechia, Germany, Denmark, Estonia, Spain, Finland, France, United Kingdom, Greece, Hungary, Ireland, Iceland, Italy, Liechtenstein, Lithuania, Latvia, Monaco, Netherlands, Poland, Portugal, Romania, Sweden, Slovenia, Slovakia, Russian Federation, Trinidad and Tobago, Singapore
Filed	Egypt	United States of America, Cyprus, Luxembourg, Norway, Finland, France, Hungary, Lithuania, Netherlands, Slovenia
Not in force	Türkiye, India, World Intellectual Property Organization (WIPO)	United States of America, Cyprus, Hong Kong, Israel, Japan, Luxembourg, Austria, Belgium, Bulgaria, Switzerland, Czechia, Germany, Denmark, Estonia, Spain, Finland, France, United Kingdom, Greece, Hungary, Ireland, Iceland, Italy, Liechtenstein, Lithuania, Latvia, Monaco, Netherlands, Poland, Portugal, Romania, Sweden, Slovenia, Slovakia, World Intellectual Property Organization (WIPO)

MPP Licence(s)

MPP Licence on Cabotegravir (tablet form and/or long-acting injectable form) for HIV pre-exposure prophylaxis (PrEP)

https://medicinespatentpool.org/licence-post/cabotegravir-long-acting-la-for-hiv-pre-exposure-prophylaxis-prep

Supporting material

Publications

Bowers GD, Culp A, Reese MJ, Tabolt G, Moss L, Piscitelli S, Huynh P, Wagner D, Ford SL, Gould EP, Pan R, Lou Y, Margolis DA, Spreen WR: Disposition and metabolism of cabotegravir: a comparison of biotransformation and excretion between different species and routes of administration in humans. Xenobiotica. 2016;46(2):147-62. doi: https://doi.org/10.3109/00498254.2015.1060372 Epub 2015 Jul 1

1. Cabotegravir [(*3S,11aR*)-*N*-[(2,4-difluorophenyl)methyl]-6-hydroxy-3-methyl-5,7-dioxo-2,3,5,7,11,11a-hexahydro[1,3]oxazolo[3,2-a]pyrido[1,2-d]pyrazine-8-carboxamide] is an HIV-1 integrase inhibitor under development as a tablet for both oral lead-in therapy and long-acting (LA) injectable for intramuscular dosing.

2. Metabolism, pharmacokinetics and excretion were investigated in healthy human subjects who received either a single oral dose (28.2 mg) of [14C]cabotegravir in a mass balance study, or LA formulations of unlabeled cabotegravir (200–800 mg), intramuscularly or subcutaneously, in a separate study. Metabolism, distribution and excretion of [14C]cabotegravir were also investigated in mice, rats and monkeys.

3. Recovery of radioactivity in humans represented a mean total of 85.3% of the dose, including 26.8% in the urine. The mean apparent terminal phase half-life was similar for both cabotegravir and radioactivity, 39 h compared to 41 h.

4. Following oral, intramuscular and subcutaneous administration, cabotegravir was the major component in plasma and the glucuronic acid conjugate (M1) represented the predominant component in urine. Cabotegravir was present in bile along with its major metabolite (M1).

5. The primary metabolite of [14C]cabotegravir in mouse, rat and monkey was the same as that in human. *In vitro* phenotyping experiments demonstrated that cabotegravir was metabolized by UDP-glucuronosyltransferase (UGT) 1A1 and UGT1A9.

Spreen W, Min S, Ford SL, Chen S, Lou Y, Bomar M, St Clair M, Piscitelli S, Fujiwara T: Pharmacokinetics, safety, and monotherapy antiviral activity of GSK1265744, an HIV integrase strand transfer inhibitor. HIV Clin Trials. 2013 Sep-Oct;14(5):192-203. doi: https://doi.org/10.1310/hct1405-192

Background: GSK1265744 is an HIV integrase strand transfer inhibitor selected for clinical development.

Objective: This first-time-in-human and phase IIa investigation assessed GSK1265744 antiviral activity, pharmacokinetics, safety, and tolerability in healthy and HIV-1-infected subjects.

Methods: This double-blind, placebo-controlled study consisted of a dose escalation of single (part A) and multiple (part B) oral doses in 48 healthy subjects and an oral dose (part C) in 11 HIV-1-infected subjects. In part A, 2 cohorts of 9 subjects received either 5 and 25 mg or 10 and 50 mg. In part B, 3 cohorts of 10 subjects received 5, 10, or 25 mg once daily for 14 days. In part C and the phase IIa study, subjects received 5 or 30 mg once daily for 10 days.

Results: Dose-proportional increases in drug exposure were observed in healthy and HIV-1-infected subjects. In healthy subjects, pharmacokinetic variability was low following single or repeat dosing (coefficient of variation, 13%-34% and 15%-23%, respectively). Mean plasma half-life was 31.5 hours. GSK1265744 monotherapy significantly reduced plasma HIV-1 RNA from baseline to day 11 in HIV-1-infected subjects receiving 5 or 30 mg versus placebo ($P < .001$); mean decrease was 2.2 to 2.3 log10 copies/mL, respectively. Study drug was generally well tolerated with no clinically relevant trends in laboratory values, vital signs, or electrocardiograms.

Conclusions: GSK1265744 was well tolerated in healthy and HIV-1-infected subjects. Results demonstrate once-daily doses of 5 or 30 mg exceeded minimum target

therapeutic concentrations and produced a significant reduction in plasma HIV-1 RNA viral load.

Trezza C, Ford SL, Spreen W, Pan R, Piscitelli S. Formulation and pharmacology of long-acting cabotegravir. Curr Opin HIV AIDS. 2015 Jul;10(4):239-45. doi: https://doi.org/10.1097%2FCOH.0000000000000168. PMID: 26049948; PMCID: PMC5638427.

Purpose of review

Long-acting cabotegravir may provide a novel therapeutic option for both the treatment and prevention of HIV-1 infection that does not necessitate adherence to a daily regimen. The present review will highlight the unique formulation properties and pharmacologic attributes of long-acting cabotegravir nanosuspension.

Recent findings

Cabotegravir is a potent integrase strand transfer inhibitor that has been formulated as an oral tablet for daily administration and as a long-acting injectable nanosuspension. Long-acting cabotegravir is readily absorbed following intramuscular and subcutaneous administration and has an elimination half-life of approximately 40 days, allowing for administration on a monthly or less frequent schedule. Repeat-dose pharmacokinetic studies and population pharmacokinetic modeling indicate monthly and bi-monthly dosing achieves clinically relevant plasma concentrations considered effective for HIV maintenance therapy and that quarterly injections are appropriate for investigation as preexposure prophylaxis. Cabotegravir is primarily metabolized by uridine diphosphate glucuronosyltransferase 1A1 and is unlikely to be impacted by the cytochrome P450 metabolic pathway. *In vitro* and *in vivo* data suggest cabotegravir has a low propensity to cause, or be subject to, significant drug interactions.

Summary

The pharmacologic profile of long-acting cabotegravir supports its continued development for both treatment and prevention of HIV-1 infection.

Additional documents

- Cabotegravir manufacturing steps
- Tentative timeline generic CAB
- posterHIVR4P

Useful links

- FDA Approves First Extended-Release, Injectable Drug Regimen for Adults Living with HIV
- GSK744 SAFETY DATA SHEET CAYMAN CHEMICALS (PDF)
- World Health Organization Guidelines on long-acting injectable cabotegravir for HIV prevention
- Injectable Cabotegravir for PrEP

Access principles

Collaborate for development

Consider on a case by case basis, collaborating on developing long acting products with potential significant public health impact, especially for low- and middle-income countries (LMICs), utilising the referred to long-acting technology

Not provided

Share technical information for match-making assessment

Provide necessary technical information to a potential partner, under confidentiality agreement, to enable preliminary assessment of whether specific medicines of public health importance in LMICs might be compatible with the referred to long-acting technology to achieve a public health benefit

Not provided

Work with MPP to expand access in LMICs

In the event that a product using the referred to long-acting technology is successfully developed, the technology IP holder(s) will work with the Medicines Patent Pool towards putting in place the most appropriate strategy for timely and affordable access in low and middle-income countries, including through licensing

Not provided

Comment & Information

Not provided