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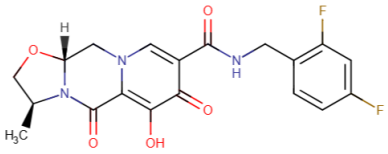


# Cabotegravir Ultra Long-Acting (CAB-ULA)

## Developer(s)

ViiV Healthcare

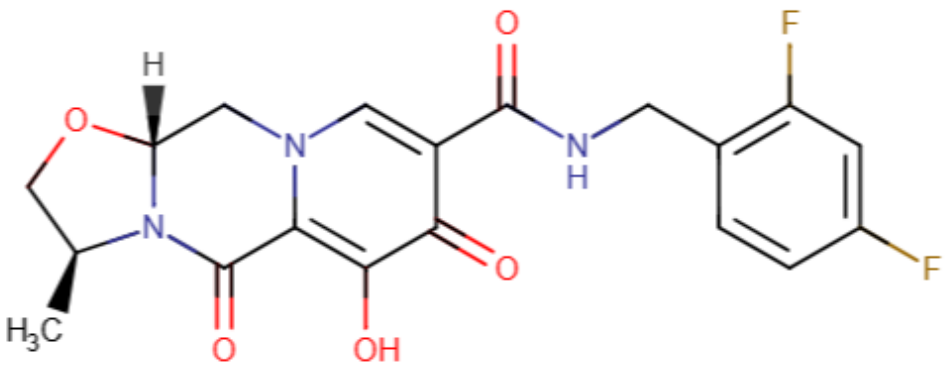
Originator

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

Subcutaneous, Intramuscular, To be determined

## Therapeutic area(s)

HIV

### Use case(s)

Pre-Exposure Prophylaxis (PrEP)
Treatment

## Use of drug

### Ease of administration

Administered by a community health worker
Administered by a nurse
Administered by a specialty health worker

### User acceptance

Not provided

## Dosage

### Available dose and strength

Formulation is in clinical development but not yet approved or commercially available. Pharmacokinetic simulations predict that a 1600 mg/3mL IM dose would be sufficient for a Q4M dosing schedule.

### Frequency of administration

Once every four months (Q4M)

### Maximum dose

1600 mg (2.7x CAB-LA)

### Recommended dosing regimen

Phase I trial evaluating safety and pharmacokinetic profile used doses at 800 mg, 1200 mg, and 1600 mg at four monthly intervals.

### Additional comments

Not provided

### Dosage link(s)

Not provided

## Drug information

### Drug's link(s)

https://go.drugbank.com/drugs/DB11751

### Generic name

Cabotegravir Ultra Long-Acting (CAB-ULA), Cabotegravir Once Four-Monthly (CAB Q4M)

### Brand name

Not provided

### Compound type

Small molecule

### Summary

Cabotegravir ultra long-acting (CAB-ULA) is an investigational injectable formulation that exhibits potential as extended-interval HIV pre-exposure prophylaxis (PrEP) and treatment. A Phase I, open-label, dose-escalation study assessed CAB-ULA's pharmacokinetics and safety in healthy adults compared to the standard 200mg/mL long-acting injectable cabotegravir formulation (CAB-LA). The maximum observed plasma concentration of CAB-ULA, regardless of route of administration, was lower than intramuscular (IM) CAB-LA at the same dose level, indicating slower absorption of CAB-ULA and the potential for four-monthly (Q4M) dosing. The projected half-life of subcutaneous CAB-ULA and IM CAB-ULA was six times greater and two times greater, respectively, than the half-life of IM CAB-LA.

### Approval status

CAB-ULA is not approved in any jurisdiction. ViiV Healthcare is currently conducting a registrational study of CAB-ULA that began in 2024 to further evaluate its use for HIV PrEP in adults. Future areas of study will include its potential use in combination with

other medicines as a complete, ultra long-acting HIV treatment regimen. The 1st Half (Interim period) of Fiscal 2024 Financial Results Report (Page 31) from Shionogi indicated a preliminary 2026 file and launch date for single-agent CAB-ULA PrEP, and in combination with Rilpivirine for HIV treatment in 2027.

### Regulatory authorities

Successful development of ultra long-acting formulations (e.g. CAB-ULA) may extend the patent protection period for cabotegravir for new LA medicines, formulations and regimens.

## Delivery device(s)

No delivery device

# Scale-up and manufacturing prospects

## Scale-up prospects

CAB-ULA is a novel formulation developed by ViiV Healthcare that doubles the concentration of cabotegravir, exhibits favourable tolerability and safety, with a PK profile that supports dose intervals of ≥4 months. Detailed manufacturing information regarding the new CAB-ULA formulation is not yet available.

## Tentative equipment list for manufacturing

Not provided

## Manufacturing

Not provided

## Specific analytical instrument required for characterization of formulation

Not provided

# Clinical trials

## EXTEND4M

### Identifier

NCT06741397

### Link

https://clinicaltrials.gov/study/NCT06741397

### Phase

Phase II

### Status

Not provided

### Sponsor

ViiV Healthcare

### More details

This study will evaluate the pharmacokinetics (PK), safety, and tolerability of a new formulation of Cabotegravir (CAB) dosed every 4-months (Q4M) for pre-exposure prophylaxis (PrEP) in participants at risk of HIV-1 acquisition.

### Purpose

A Study to Evaluate the Pharmacokinetics, Safety, and Tolerability of a New Formulation of Cabotegravir Long-Acting Administered Intramuscularly in a 4-month Dosing Interval (Q4M)

## Interventions

### Intervention 1

Drug: CAB LA administered IM gluteal

### Intervention 2

Drug: New formulation of CAB LA administered IM gluteal

## Countries

Puerto Rico

United States of America

## Sites / Institutions

Not provided

## Trials dates

### Anticipated Start Date

Not provided

### Actual Start Date

2024-12-20

### Anticipated Date of Last Follow-up

2025-04-01

### Estimated Primary Completion Date

2026-09-03

### Estimated Completion Date

2028-12-28

### Actual Primary Completion Date

Not provided

### Actual Completion Date

Not provided

## Studied populations

### Age Cohort

- Children
- Adults
- Older Adults

### Genders

- All

### Accepts pregnant individuals

No

### Accepts lactating individuals

No

### Accepts healthy individuals

Yes

## Comments about the studied populations

Inclusion Criteria: 1. At the time of obtaining informed consent, adolescent and adult participants weighing at least 35 kg. 2. Participants must have a nonreactive HIV test at Screening (rapid test, nonrapid HIV immunoassay, and HIV RNA) and enrollment (a rapid test, nonrapid HIV immunoassay, and HIV RNA). 3. Participants who are at risk of acquiring HIV, defined as having had anal or vaginal sex in the past 6 months. 4. 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 at the time of screening. 5. No alcohol or substance use that, in the opinion of the study investigator and medical monitor, would interfere with the study.

## Health status

Negative to : HIV, HBV
Considered high risk to :

## Study type

Interventional (clinical trial)

## Enrollment

191

## Allocation

Randomized

## Intervention model

Single group assignment

## Intervention model description

Not provided

## Masking

Open label

## Masking description

This is an open label study.

## Frequency of administration

Other(s) : "Once Every Four Months "

## Studied LA-formulation(s)

Injectable

## Studied route(s) of administration

Intramuscular

## Use case

PrEP

## Key results

Not provided

# 223369

## Identifier

NCT06786520

## Link

https://clinicaltrials.gov/study/NCT06786520

## Phase

Phase I

## Status

Recruiting

## Sponsor

ViiV Healthcare

## More details

This study will assess the pharmacokinetics (PK), safety, and tolerability of CAB ULA administered every 4 months (Q4M) following administration of CAB LA every 2 months (Q2M), in healthy adult volunteers.

## Purpose

A Study to Evaluate the Pharmacokinetics, Safety, and Tolerability of Cabotegravir Ultra Long-acting (CAB ULA) Following Switch From Cabotegravir Long-acting (CAB LA) in Healthy Adults

## Interventions

### Intervention 1

Drug: CAB LA

**Intervention 2**

Drug: CAB ULA

Dosage: 800 mg, 1200 mg, and 1600 mg

## Countries

United States of America

## Sites / Institutions

Not provided

## Trials dates

**Anticipated Start Date**

Not provided

**Actual Start Date**

2025-01-17

**Anticipated Date of Last Follow-up**

2025-02-17

**Estimated Primary Completion Date**

2027-02-17

**Estimated Completion Date**

2028-02-29

**Actual Primary Completion Date**

Not provided

**Actual Completion Date**

Not provided

## 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

Inclusion Criteria: * Adult participants greater than or equal to (\>=) 18 years old, weighing at least 35 kg. * Participants who are overtly healthy as determined by medical evaluation. * Assigned male sex at birth or assigned female sex at birth. Participants assigned female sex at birth are eligible to participate if they are of non-childbearing potential, or if they are of childbearing potential and are not pregnant (confirmed by test), not breastfeeding, and are using a highly effective contraceptive method. * Capable of giving written informed consent.

## Health status

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

## Study type

Interventional (clinical trial)

## Enrollment

60

## 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(s) : "Once Every Four Months "

## Studied LA-formulation(s)

Injectable

## Studied route(s) of administration

Subcutaneous
Intramuscular

## Use case

PrEP

## Key results

Not provided

# Excipients

## Proprietary excipients used

Not provided

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

Not provided

## Residual solvents used

Not provided

# Patent info

There are either no relevant patents or these were not yet submitted to LAPaL

# Supporting material

## Publications

There are no publication

## Additional documents

No documents were uploaded

## Useful links

- ViiV Healthcare presents phase I clinical trial findings of a cabotegravir long-acting injectable investigational formulation allowing at least four months between doses
- Phase 1 Study of Cabotegravir Long-Acting Injectable Formulations Supports ≥4-Monthly Dose Interval

# 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