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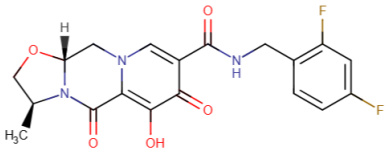


Cabotegravir 4-monthly (Q4M)

Developer(s)

ViiV Healthcare

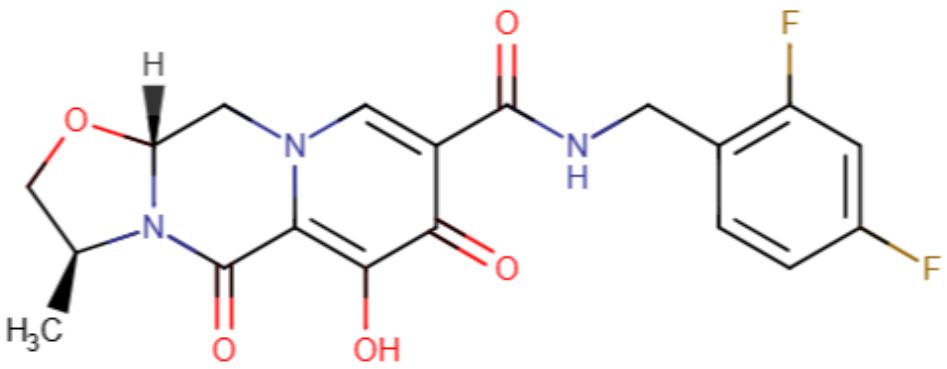
Originator

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. Phase 3 trial experimental arm: Participants received lead-in injections comprising cabotegravir LA during month one and injections of a new formulation of CAB LA at Month 3, Month 5 and every 4 months thereafter to Month 29.

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

Active, not recruiting

Sponsor

ViiV Healthcare

More details

A single arm, repeat dose study to evaluate the pharmacokinetic profile, safety, and tolerability of a new formulation of cabotegravir LA injected intramuscularly Q4M in adolescent and adult participants at risk of HIV 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

CAB LA administered IM gluteal

Intervention 2

New formulation of CAB LA (4M) 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 :
Other health status: The study enrolled healthy adolescent and adult participants

Study type

Interventional (clinical trial)

Enrollment

191

Allocation

Randomized

Intervention model

Single group assignment

Intervention model description

Key end point: CAB trough concentrations Participants receive lead-in injections comprising cabotegravir LA during month one and injections of a new formulation of CAB LA at Month 3, Month 5 and every 4 months thereafter to Month 29

Masking

Open label

Masking description

This is an open label study.

Frequency of administration

Other : "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

A single arm, repeat dose study to evaluate the pharmacokinetics, safety, and tolerability of switching to cabotegravir long-acting 4-monthly formulation (CAB Q4M) from cabotegravir long-acting (CAB LA 2M) 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 (2M)

Intervention 2

Drug: CAB LA (4M formulation)

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
Other health status: The study enrolled healthy adults

Study type

Interventional (clinical trial)

Enrollment

60

Allocation

Not provided

Intervention model

Single group assignment

Intervention model description

Participants will receive the CAB LA Q2M regimen up to Month 9 then will receive the CAB ULA Q4M regimen up to Month 23. Key end points are plasma concentration of CAB at the end of the CAB LA 2M phase compared to plasma concentration of CAB at the end of the CAB Q4M phase

Masking

Open label

Masking description

None (Open Label)

Frequency of administration

Other : "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

Compound patent families

Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Cabotegravir ultra-long acting formulations II Expiry date: 2044-09-25 The present invention relates to Human Immunodeficiency Virus (HIV) prevention and treatment. In particular, the invention relates to a pharmaceutical composition comprising: cabotegravir; a wetting agent; a stabilizer; and a tonicity adjuster; wherein cabotegravir is present in the form of particles having a mass median diameter (X50) of between (and including) 2.5 µm and 10 µm.	WO2025068912	Composition	ViiV Healthcare Company	No	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted		
Filed	World Intellectual Property Organization (WIPO)	World Intellectual Property Organization (WIPO), United States of America
Not in force		

Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Cabotegravir ultra-long acting formulations I Expiry date: 2043-09-27 The present invention relates to Human Immunodeficiency Virus (HIV) prevention and treatment. In particular, the invention relates to a pharmaceutical composition comprising: cabotegravir; a wetting agent; a stabilizer; and a tonicity adjuster; wherein cabotegravir is present in the form of particles having a mass median diameter (X50) of between (and including) 2.5 µm and 10 µm.	WO2025068743	Composition	ViiV Healthcare Company	No	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted		
Filed	World Intellectual Property Organization (WIPO)	World Intellectual Property Organization (WIPO)
Not in force		

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	No	

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)

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	No	

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)

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