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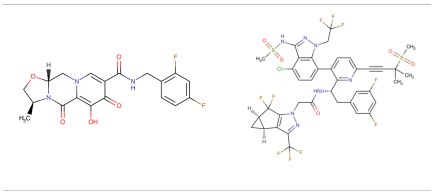


Cabotegravir + Lenacapavir

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.

Gilead Sciences, Inc.

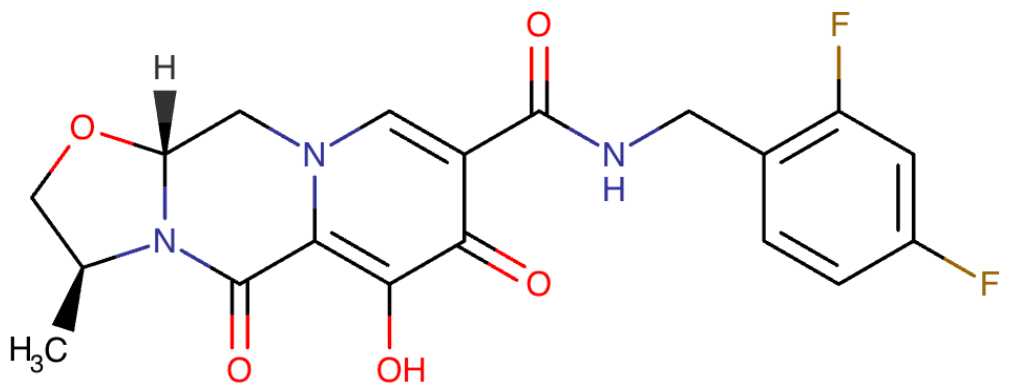
Originator

https://www.gilead.com/

United States

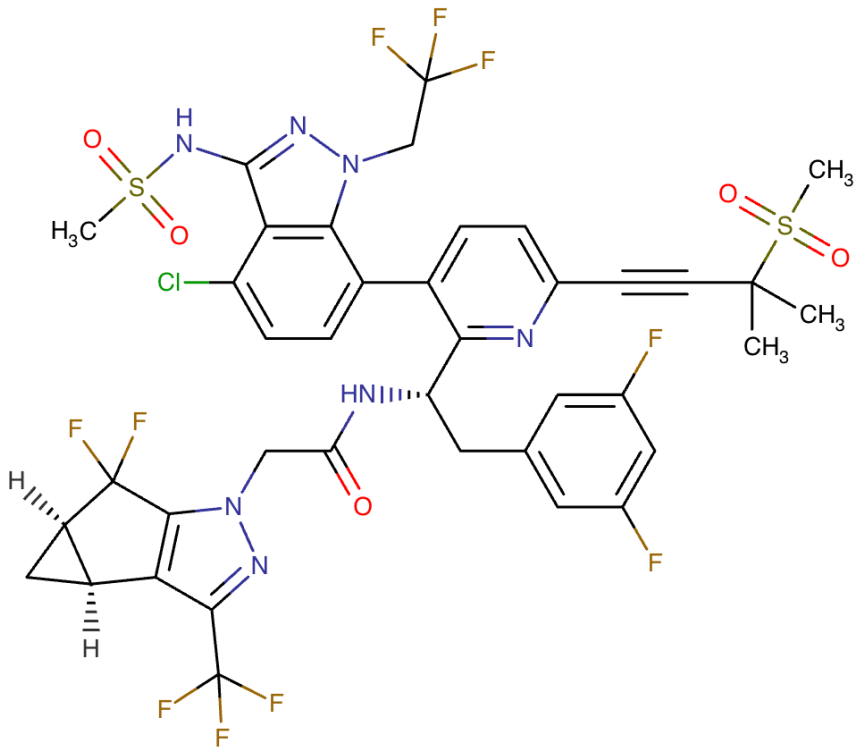
Gilead Sciences, Inc. is a multinational biopharmaceutical company that develops and manufactures innovative medicines for life-threatening diseases, including anti-viral therapeutics for HIV/AIDS, Hepatitis B, Hepatitis C and Covid-19. Headquartered in Foster City, California, Gilead was originally founded in 1987 and is currently listed on both the S&P 500 and the NASDAQ Biotechnology Index.

Drug structure



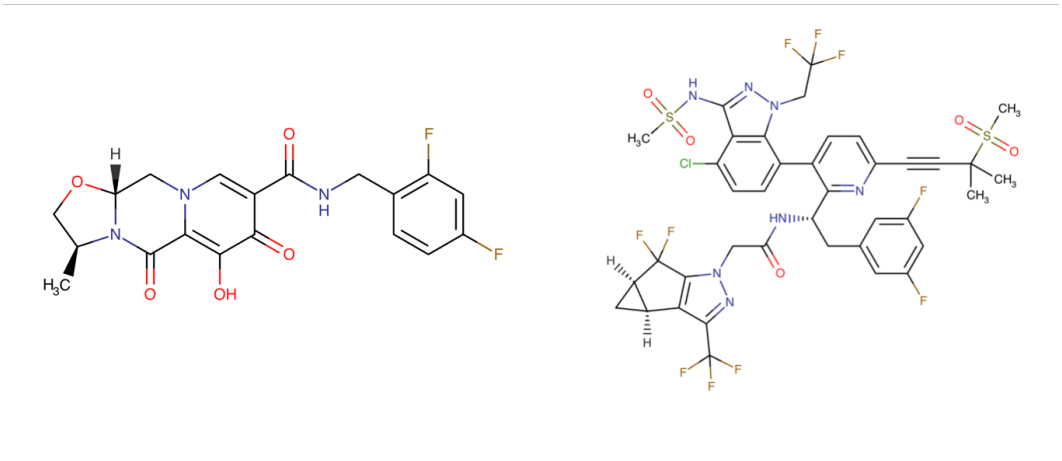
Cabotegravir Chemical Structure

Sourced From DrugBank



Lenacapavir Chemical Structure

Sourced From DrugBank



Cabotegravir and Lenacapavir Chemical Structure

Composite adapted from individual chemical structures sourced from DrugBank

Drug information

Associated long-acting platforms

Aqueous drug particle suspension, Aqueous solution

Administration route

Subcutaneous, Intramuscular

Therapeutic area(s)

HIV

Use case(s)

Treatment

Use of drug

Ease of administration

Administered by a community health worker
Administered by a nurse

Frequency of administration

Not provided

User acceptance

Not provided

Dosage

Available dose and strength

Not provided

Maximum dose

Not provided

Recommended dosing regimen

Not provided

Additional comments

Not provided

Dosage link(s)

Not provided

Drug information

Drug's link(s)

https://go.drugbank.com/drugs/DB11751
https://go.drugbank.com/drugs/DB15673

Generic name

Cabotegravir and Lenacapavir

Brand name

Apretude (CAB), Vocabria (CAB), Sunlenca (LEN)

Compound type

Small molecule

Drug class/category

INSTI+capsid inhibitor

Summary

Cabotegravir and Lenacapavir (CAB/LEN) is an investigational drug combination in clinical development for the treatment of HIV-1. Currently, the only approved complete long-acting ART therapy regimen in both the U.S. and Europe is a combination of intramuscular CAB and rilpivirine (CAB/RPV). This regimen is approved for individuals with prior viral suppression on oral ART. LEN is a novel HIV-1 capsid inhibitor administered via subcutaneous injection every 26 weeks and has recently been

approved for the treatment of multidrug-resistant (MDR) HIV. While it has been studied in both treatment-naïve (CALIBRATE study) and MDR individuals (CAPELLA), the use of LEN in combination with CAB LA for individuals with NNRTI resistance and/or oral ART adherence challenges is currently being evaluated.

Approval status

Given the limited number of available LA-ART medications, healthcare providers are increasingly prescribing injectable LEN through insurance programs and using it off-label with LA CAB (+/- RPV) for select patients with adherence challenges and NNRTI resistance.

Regulatory authorities

Unknown

Delivery device(s)

No delivery device

Scale-up and manufacturing prospects

Scale-up prospects

Cabotegravir is commercially manufactured by the innovator (ViiV Healthcare) and three generic manufacturers have received a licence through the Medicines Patent Pool to manufacture generic versions by 2026/2027. Lenacapavir is commercially manufactured by Gilead Sciences Inc.

Tentative equipment list for manufacturing

Cabotegravir: Conventional wet-bead milling (ball mill), depyrogenated glass vials. Lenacapavir: Equipment: Stainless steel pharmaceutical reactors, glass-lined reactors, rotary evaporator (rotovap), flash chromatography columns, stainless steel autoclave, cooling bath, silica gel chromatography columns, vacuum distillation apparatus, simulated moving bed chromatography system, Chiralpak columns.

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. Storage of injectable lenacapavir in borosilicate vials is contraindicated due to issues with chemical compatibility. Instead, it is recommended that vials are made from aluminosilicate glass.

Specific analytical instrument required for characterization of formulation

Cabotegravir: 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. Lenacapavir: Proton nuclear magnetic resonance (1H NMR), High-performance liquid chromatography (HPLC), Ultra-Performance Liquid Chromatography (UPLC).

Clinical trials

CALENDULA

Identifier

NCT06657885

Link

https://clinicaltrials.gov/study/NCT06657885

Phase

Marketed

Status

Withdrawn

Sponsor

Institut de Médecine et d'Epidémiologie Appliquée - Fondation Internationale Léon M'Ba

More details

This study is a Phase II, prospective, single-arm, multicenter, non-randomized pilot study designed to evaluate the antiretroviral efficacy of lenacapavir in combination with cabotegravir injection over 48 weeks of follow-up in participants who meet the study inclusion criteria. Efficacy is defined as the absence of virologic failure at S48. Virologic success is defined as maintaining or achieving CV \< 50 copies/mL without

interruption of long-acting dual therapy with cabotegravir/lenacapavir at the end of 48 weeks. The study will be conducted at several sites in France in adults 18 years of age and older. The study stopped early, before enrolling its first participant. Reason stated as of 14 Jan. 2026 is "No response regarding coverage of treatments by social security and the DGOS"

Purpose

CAbotégravir LENacapavir DUal Long Acting

Interventions

Intervention 1
Drug: Cabotegravir (Initiation) Oral Tablet
Dosage: 30 mg

Intervention 2
Drug: Cabotegravir (Maintenance) Intramuscular Injection
Dosage: N/A (Every 8 weeks)

Intervention 3
Drug: Lenacapavir (Initiation) Subcutaneous injection
Dosage: Two injections of 463.5mg/1.5mL in distinct abdominal sites

Intervention 4
Drug: Lenacapavir (Initiation)
Dosage: Two 300mg tablets

Intervention 5
Drug: Lenacapavir (Maintenance) Subcutaneous Injection
Dosage: Two injections of 463.5mg/1.5mL in distinct abdominal sites every 24 weeks

Countries

France

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

2025-01-15

Actual Start Date

Not provided

Anticipated Date of Last Follow-up

2026-01-12

Estimated Primary Completion Date

2026-07-15

Estimated Completion Date

2026-09-15

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

No

Comments about the studied populations

Inclusion: - Age ≥ 18 years - HIV-1 infection - Stable oral antiretroviral treatment for at least 6 months - Multi-treated patients who have received multiple lines of antiretroviral treatment - Undetectable patients with CV \< 50 copies/mL in the last 6 months (a single blip between 50 and 200 copies/mL in the last 6 months is allowed) and eligible to switch to the lenacapavir/cabotegravir strategy on the basis of a collegial decision by clinicians, virologists and pharmacologists following a multidisciplinary meeting due to the presence of resistance mutations, including to NNRTIs, oral drug intolerance or drug-drug interactions - Detectable, virologically uncontrolled HIV viral load ≥ 200 c/mL in the last 12 months who is eligible to switch to the lenacapavir/cabotegravir strategy

Health status

Positive to : HIV
Negative to : HBV, HCV

Study type

Interventional (clinical trial)

Enrollment

Not provided

Allocation

Non-randomized

Intervention model

Single group assignment

Intervention model description

Not provided

Masking

Open label

Masking description

None (Open Label)

Frequency of administration

Every 6 months
Every 2 months

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Subcutaneous
Intramuscular

Use case

Treatment

Key resources

Type	Title	Content	Link
Link	Rapport d'activité IMEA		https://www.imea.fr/uploads

CLARITY

Identifier

NCT06970223

Link

https://clinicaltrials.gov/study/NCT06970223

Phase

Phase I

Status

Not provided

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

Intervention 1

Cabotegravir long-acting

Intervention 2

Lenacapavir long-acting

Countries

United States of America

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2025-04-22

Anticipated Date of Last Follow-up

2025-07-16

Estimated Primary Completion Date

2025-07-30

Estimated Completion Date

2026-07-10

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

57

Allocation

Randomized

Intervention model

Cross-over assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Every 2 months

Every 6 months

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Subcutaneous
Intramuscular

Use case

Treatment

Key resources

Not provided

A5433-LANCET

Identifier

Not provided

Link

Not provided

Phase

Phase III

Status

Not yet recruiting

Sponsor

ACTG - NIH

More details

In those failing TLD due to adherence difficulties without suspicion for resistance (superiority study). To be conducted in LMICs

Purpose

Randomised study using injectable LEN+CAB vs. daily oral TLD with enhanced adherence counselling

Interventions

Not provided

Countries

Brazil
Botswana
South Africa

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date
2026-02-01

Actual Start Date
Not provided

Anticipated Date of Last Follow-up
Not provided

Estimated Primary Completion Date
Not provided

Estimated Completion Date
2028-02-01

Actual Primary Completion Date
Not provided

Actual Completion Date
Not provided

Studied populations

Age Cohort

- Adults

Genders

Unspecified

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

Unspecified

Comments about the studied populations

Not provided

Health status

Positive to : HIV

Study type

Not provided

Enrollment

Not provided

Allocation

Not provided

Intervention model

Not provided

Intervention model description

Not provided

Masking

Not provided

Masking description

Not provided

Frequency of administration

Every 2 months
Every 6 months

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Subcutaneous
Intramuscular

Use case

Treatment

Key resources

Not provided

A5431-PALACE

Identifier

Not provided

Link

Not provided

Phase

Phase III

Status

Not yet recruiting

Sponsor

ACTG-NIH

More details

Not provided

Purpose

Not provided

Interventions

Not provided

Countries

United States of America

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

Not provided

Anticipated Date of Last Follow-up

Not provided

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

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

Unspecified

Comments about the studied populations

Inclusion criteria: •NNRTI resistance •Vireamic •Experiencing adherence challenges with oral ART

Health status

Positive to : HIV

Study type

Not provided

Enrollment

38

Allocation

Non-randomized

Intervention model

Single group assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Every 2 months
Every 6 months

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Subcutaneous
Intramuscular

Use case

Treatment

Key resources

Not provided

POA

Identifier

Not provided

Link

Not provided

Phase

Phase III

Status

Not yet recruiting

Sponsor

EDCTP

More details

Objectives: 1- Determine the non-inferiority of injectable LEN/CAB compared to daily oral TLD (standard of care) in 2 populations: - population 1: for the maintenance of first-line ART in adult PLHIV at risk of failure - population 2: in treatment naive PLHIV starting first-line ART (leading with TLD is discussed for the LEN/CAB arm) 2- describe the implementation context and fidelity of implementing injectable LA ART 3- understand pharmacokinetics 4- describe cost-effectiveness

Purpose

Pragmatic Use of long-acting Antiretrovirals in Africa (POA)

Interventions

Intervention 1

CAB + LEN

Intervention 2

daily orl TLD

Countries

Uganda

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

2026-03-01

Actual Start Date

Not provided

Anticipated Date of Last Follow-up

Not provided

Estimated Primary Completion Date

Not provided

Estimated Completion Date

2028-06-01

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adolescents
- Adults

Genders

- All

Accepts pregnant individuals

Yes

Accepts lactating individuals

Yes

Accepts healthy individuals

No

Comments about the studied populations

Age > 12 years

Health status

Positive to : HIV

Study type

Interventional (clinical trial)

Enrollment

Not provided

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Every 2 months
Every 6 months

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Subcutaneous

Intramuscular

Use case

Treatment

Key resources

Not provided

CALENDULA bis

Identifier

NCT07402044

Link

https://clinicaltrials.gov/study/NCT07402044

Phase

Marketed

Status

Not yet recruiting

Sponsor

Institut de Médecine et d'Epidémiologie Appliquée - Fondation Internationale Léon M'Ba

More details

The main objective of this national study is to evaluate the virological success of long-acting antiretroviral therapy combining cabotegravir and lenacapavir. The study involves patients who have been receiving this treatment for one year or those for whom the physician decides to initiate it. It also aims to evaluate the tolerability of the treatment and changes in the participants' immunovirological profile during follow-up.

Purpose

CABOTEGRAVIR/LENACAPAVIR DUAL LONG ACTING THERAPY (COHORT IMEA 074)

Interventions

Intervention 1

cabotegravir (2M IM) + lenacapavir (6M IM)

Countries

France

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

2026-02-15

Actual Start Date

Not provided

Anticipated Date of Last Follow-up

2026-02-03

Estimated Primary Completion Date

2028-02-15

Estimated Completion Date

2028-02-15

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

No

Comments about the studied populations

Not provided

Health status

Positive 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

Every 6 weeks
Every 2 months

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Subcutaneous
Intramuscular

Use case

Treatment

Key resources

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

Formulation patent families

Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Lenacapavir use in HIV pre-exposure prophylaxis (PrEP) Expiry date: 2040-11-25 The present disclosure provides methods of preventing HIV in a subject, comprising administering to the subject a therapeutically effective amount of compounds of Formula (la) or (lb) or a pharmaceutically acceptable salt thereof, optionally in combination with one or more additional therapeutic agents. Methods of reducing the risk of acquiring HIV (e.g, HIV-1 and/or HIV-2) are also provided.	WO2021108544	Use	Gilead Sciences, Inc	No	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted		Australia, United States of America

Patent status/countries	Low, Low- middle and upper-middle	High income
Filed	China, Albania, Serbia, Türkiye, North Macedonia, India	Australia, Canada, 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, Taiwan, Province of China, United States of America, Hong Kong
Not in force	World Intellectual Property Organization (WIPO), Morocco, Tunisia, Bosnia and Herzegovina, Cambodia, Montenegro, Moldova, Republic of	World Intellectual Property Organization (WIPO), Japan, Korea, Republic of, United States of America

Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Lenacapavir use to treat multidrug resistant HIV infection in heavily treatment-experienced Expiry date: 2039-07-15 The present disclosure relates to compounds of Formula (Ia) and (Ib) or a pharmaceutically acceptable salt thereof, which are useful in the treatment of an HIV infection in heavily treatment-experienced patients with multidrug resistant HIV infection.	WO2020018459	Use	Gilead Sciences, Inc	No	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted		Australia, United States of America
Filed	China, Albania, Serbia, Türkiye, North Macedonia	Australia, Canada, 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, Korea, Republic of, Taiwan, Province of China
Not in force	World Intellectual Property Organization (WIPO), Morocco, Tunisia, Bosnia and Herzegovina, Cambodia, Montenegro, Moldova, Republic of	World Intellectual Property Organization (WIPO), Australia, Canada, Japan, Korea, Republic of

Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Lenacapavir manufacturing processess and intermediates Expiry date: 2039-02-15 The present disclosure relates to methods and intermediates useful for preparing a compound of formula (I): (I) or a co-crystal, solvate, salt or combination thereof.	WO2019161280	Intermediate(s), Process	Gilead Sciences, Inc	No	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted	China, Türkiye, India	Australia, Liechtenstein, Italy, Norway, Malta, Denmark, Belgium, United Kingdom, Greece, Netherlands, Switzerland, Spain, Slovenia, Austria, Finland, France, Bulgaria, Slovakia, Poland, Latvia, Ireland, Estonia, Germany, Luxembourg, Portugal, Czechia, Sweden, Japan, Korea, Republic of, Taiwan, Province of China, United States of America, Hong Kong
Filed	China, Albania, Serbia, Türkiye, North Macedonia, India	Australia, Canada, 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, Taiwan, Province of China, United States of America

Patent status/countries	Low, Low- middle and upper-middle	High income
Not in force	World Intellectual Property Organization (WIPO), Argentina, Morocco, Tunisia, Albania, Serbia, Bosnia and Herzegovina, Cambodia, Montenegro, Moldova, Republic of, North Macedonia	World Intellectual Property Organization (WIPO), Hungary, Croatia, San Marino, Romania, Iceland, Cyprus, Lithuania, Monaco, Bahamas

Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Crystalline forms of Lenacapavir sodium salt Expiry date: 2038-08-16 Lenacapavir solid forms, including pharmaceutically acceptable salts and cocrystals of the inhibitor, as well as crystalline forms of the salts and cocrystals, for use in the treatment of a Retroviridae viral infection including an infection caused by the HIV virus. The present disclosure also relates to pharmaceutical compositions containing the novel salts, cocrystals, and crystalline forms thereof, and methods of treating or preventing a Retroviridae viral infection.	WO2019035904	Polymorphs	Gilead Sciences, Inc	No	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted	Türkiye	Belgium, Germany, France, Luxembourg, Netherlands, Switzerland, United Kingdom, Sweden, Italy, Austria, Liechtenstein, Greece, Spain, Denmark, Portugal, Ireland, Finland, Cyprus, Bulgaria, Czechia, Estonia, Slovakia, Poland, Malta, Norway, Romania, Latvia, Lithuania, Slovenia, Australia, Canada, Japan, Korea, Republic of, Taiwan, Province of China, United States of America, Hong Kong

Patent status/countries	Low, Low- middle and upper-middle	High income
Filed	Türkiye, North Macedonia, Albania, Serbia, China, India	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, Canada, Hong Kong
Not in force	World Intellectual Property Organization (WIPO), North Macedonia, Albania, Bosnia and Herzegovina, Montenegro, Serbia, Moldova, Republic of, Morocco, Tunisia, Cambodia, Argentina, Bangladesh	World Intellectual Property Organization (WIPO), Luxembourg, Denmark, Monaco, Finland, Cyprus, Bulgaria, Estonia, Hungary, Iceland, Malta, San Marino, Croatia, Romania, Latvia, Lithuania, Japan, Taiwan, Province of China

Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Lenacapavir compound and its use in HIV (oral and parenteral) Expiry date: 2037-08-17 The present disclosure relates to novel compounds for use in the treatment of a Retroviridae viral infection including an infection caused by the HIV virus. The present disclosure also relates to intermediates for its preparation and to pharmaceutical compositions containing said novel compound.	WO2018035359	Compound	Gilead Sciences, Inc	No	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted	Türkiye, Morocco, Brazil, China, Colombia, Dominican Republic, Turkmenistan, Belarus, Tajikistan, Kazakhstan, Azerbaijan, Kyrgyzstan, Armenia, Mexico, Peru, Philippines, Botswana, Gambia (the), Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Liberia, Sao Tome and Principe, Sudan, Eswatini, Tanzania, United Republic of, Zambia, Zimbabwe, Indonesia, Malaysia, Ukraine, South Africa, Uzbekistan	Belgium, Germany, France, Luxembourg, Netherlands, Switzerland, United Kingdom, Sweden, Italy, Austria, Liechtenstein, Greece, Spain, Denmark, Portugal, Ireland, Finland, Cyprus, Bulgaria, Czechia, Estonia, Slovakia, Hungary, Poland, Iceland, Malta, Norway, Croatia, Romania, Latvia, Lithuania, Slovenia, Australia, Canada, Costa Rica, Russian Federation, Hong Kong, Israel, Japan, Korea, Republic of, New Zealand, Singapore, Taiwan, Province of China, United States of America, Bahamas, Bahrain, Kuwait, Qatar, Saudi Arabia, Oman, United Arab Emirates, Macao, Panama

Patent status/countries	Low, Low- middle and upper-middle	High income
Filed	Türkiye, North Macedonia, Albania, Serbia, Morocco, Argentina, China, Jordan, Philippines, India, Uganda, Egypt, Guatemala, Indonesia, Nigeria, Thailand, Ukraine, Viet Nam	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, Australia, Hong Kong, Korea, Republic of, Singapore, Taiwan, Province of China, United States of America, Saudi Arabia, Panama
Not in force	World Intellectual Property Organization (WIPO), North Macedonia, Albania, Bosnia and Herzegovina, Montenegro, Serbia, Moldova, Republic of, Morocco, Argentina, Colombia, Dominican Republic, Ecuador, Peru, Rwanda, Uganda, Bangladesh, Bolivia (Plurinational State of), Cuba, Egypt, Benin, Cameroon, Burkina Faso, Chad, Guinea-Bissau, Comoros, Mali, Senegal, Congo, Guinea, Gabon, Niger, Equatorial Guinea, Mauritania, Togo, Côte d'Ivoire, Central African Republic, Pakistan, Paraguay, El Salvador, Venezuela (Bolivarian Republic of)	World Intellectual Property Organization (WIPO), Monaco, Malta, San Marino, Chile, Japan, Korea, Republic of, Uruguay, Trinidad and Tobago

Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Lenacapavir and analogues (Markush formula) and their use in HIV Expiry date: 2034-02-28 Compounds of formula (I) or salts thereof are disclosed. Also disclosed are pharmaceutical compositions comprising a compound of formula I, processes for preparing compounds of formula I, intermediates useful for preparing compounds of formula I and therapeutic methods for treating a Retroviridae viral infection including an infection caused by the HIV virus.	WO2014134566	Compound	Gilead Sciences, Inc	No	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted	Türkiye, North Macedonia, Albania, Bosnia and Herzegovina, Montenegro, Serbia, Brazil, China, Cuba, Turkmenistan, Belarus, Tajikistan, Kazakhstan, Azerbaijan, Kyrgyzstan, Armenia, Mexico, Peru, Philippines, Ukraine, Botswana, Gambia (the), Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Liberia, Rwanda, Sudan, Eswatini, Tanzania, United Republic of, Zambia, Zimbabwe, Benin, Cameroon, Burkina Faso, Chad, Guinea-Bissau, Comoros, Mali, Senegal, Congo, Guinea, Gabon, Niger, Equatorial Guinea, Mauritania, Togo, Côte d'Ivoire, Central African Republic, Colombia, Indonesia, Malaysia, Viet Nam, South Africa	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, Australia, Canada, Chile, Costa Rica, Russian Federation, Hong Kong, Israel, Japan, Korea, Republic of, New Zealand, Singapore, Taiwan, Province of China, United States of America, Bahrain, Kuwait, Qatar, Saudi Arabia, Oman, United Arab Emirates, Macao, Panama

Patent status/countries	Low, Low- middle and upper-middle	High income
Filed	Türkiye, North Macedonia, Albania, Serbia, Argentina, Ukraine, India, Egypt, Thailand	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, United States of America
Not in force	World Intellectual Property Organization (WIPO), North Macedonia, Albania, Bosnia and Herzegovina, Montenegro, Serbia, Argentina, Brazil, China, Moldova, Republic of, Peru, Uganda, Bolivia (Plurinational State of), Colombia, Ecuador, Malaysia, Paraguay, Pakistan, El Salvador, Venezuela (Bolivarian Republic of), Viet Nam, South Africa	World Intellectual Property Organization (WIPO), Luxembourg, Denmark, Monaco, Finland, Cyprus, Bulgaria, Estonia, Malta, San Marino, Croatia, Romania, Latvia, Lithuania, Australia, Canada, Costa Rica, Hong Kong, Japan, New Zealand, Singapore, United States of America, Uruguay, Bahamas

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	No	

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		
Not in force	World Intellectual Property Organization (WIPO)	World Intellectual Property Organization (WIPO), United States of America

Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Cabotegravir or dolutegravir 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, Singapore, Taiwan, Province of China, United States of America
Filed		
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, Hong Kong, Israel, Japan, Korea, Republic of, Luxembourg, Norway, New Zealand, Taiwan, Province of China, Austria, Belgium, Bulgaria, Switzerland, Cyprus, 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, Gibraltar, Guernsey, Jersey
Filed	Egypt	United States of America, Luxembourg, Norway, Cyprus, Finland, Netherlands, Slovenia
Not in force	Türkiye, India, World Intellectual Property Organization (WIPO)	United States of America, Hong Kong, Israel, Japan, Luxembourg, Austria, Belgium, Bulgaria, Switzerland, Cyprus, 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

Gandhi M, Hill L, Grochowski J, Nelson A, Koss CA, Mayorga-Munoz F, Oskarsson J, Shiels M, Avery A, Bamford L, Baron J, Short WR, Hileman CO. **Case Series of People With HIV on the Long-Acting Combination of Lenacapavir and Cabotegravir: Call for a Trial**. Open Forum Infect Dis. 2024 Apr 16;11(4):ofae125. DOI: 10.1093/ofid/ofae125. PMID: 38628952; PMCID: PMC11020301.

Background

Injectable cabotegravir (CAB)/rilpivirine (RPV) is the only combination long-acting (LA) antiretroviral regimen approved for HIV. RPV may not be effective among individuals with non-nucleoside reverse transcriptase inhibitor (NNRTI) resistance, which has >10% prevalence in many countries. Lenacapavir (LEN) is an LA capsid inhibitor given every 6 months, but has not been studied in combination with other LA agents.

Methods

We assembled a case series from 4 US academic medical centers where patients with adherence challenges were prescribed LEN subcutaneously every 26 weeks/CAB (+/− RPV) intramuscularly every 4 or 8 weeks. Descriptive statistics, including viral load (VL) outcomes, were summarized.

Results

All patients (n = 34: 76% male; 24% cis/trans female; 41% Black; 38% Latino/a; median age [range], 47 [28–75] years; 29% and 71% on CAB every 4 or 8 weeks) reported challenges adhering to oral ART. The reasons for using LEN/CAB with or without RPV were documented or suspected NNRTI mutations (n = 21, 59%), integrase mutations (n = 5, 15%), high VL (n = 6, 18%), or continued viremia on CAB/RPV alone (n = 4, 12%). Injection site reactions on LA LEN were reported in 44% (32% grade I,

12% grade 2). All patients but 2 (32/34; 94%) were suppressed (VL <75 copies/mL) after starting LEN at a median (range) of 8 (4–16) weeks, with 16/34 (47%) suppressed at baseline.

Conclusions

In this case series of 34 patients on LEN/CAB, high rates of virologic suppression (94%) were observed. Reasons for using LEN/CAB included adherence challenges and underlying resistance, mostly to NNRTIs. These data support a clinical trial of LEN/CAB among persons with NNRTI resistance.

Phillips, A., Smith, J., Bansi-Matharu, L. *et al.* **Potential impact and cost-effectiveness of long-acting injectable lenacapavir plus cabotegravir as HIV treatment in Africa**. *Nat Commun* **16**, 5760 (2025). https://doi.org/10.1038/s41467-025-60752-y

Although viral suppression is attained for most adults living with diagnosed HIV in East, Central, Southern and West Africa (ECSWA), challenges remain with sustained adherence to daily oral pill taking for some in the population. Here, we evaluate the potential effectiveness and cost-effectiveness of introduction of a new combination of long-acting injectable drugs of lenacapavir + cabotegravir to increase levels of sustained viral suppression. We find there is potential for a significant impact on HIV deaths and disability adjusted life years, including due to a decrease in mother to child transmission. If lenacapavir + cabotegravir can be sourced at a cost of around $ 80 per year or less, our analysis suggests there is potential for a policy to introduce it to be cost-effective in settings in ECSWA. Recognising the limitations of a modelling study, we suggest that implementation studies be conducted to confirm the viability of these approaches.

Long-acting cabotegravir plus lenacapavir as a fully injectable maintenance antiretroviral regimen in people with HIV with adherence issues. Glasgow 2024, Abstract P058. Romain **Palich**, Romain Manchon, Jérémy Zeggagh, Elisabete Gomes-Pires, Sophie Seang, Marc-Antoine Valantin, Marc Wirden, Marianne Burgard,

Gilles Peytavin, Claudine Duvivier

Background: Long-acting injectable (LAI) antiretroviral therapy (ART) represents a breakthrough in managing HIV, providing an alternative to daily oral ART, especially for PLWH with adherence challenges. However, the use of LAI-cabotegravir (CAB) in association with LAI-rilpivirine (RPV) is contraindicated in PLWH with previous RPV-associated resistance mutations. LAI-lenacapavir (LEN) may help address barriers to treatment adherence among PLWH with RPV-resistant virus.

Methods: In this series, we report on eight pretreated virally suppressed (plasma viral load [pVL] <50 copies/ml) adult PLWH with RPV-resistant virus, who started LAI-ART with CAB plus LEN between January 2021 and August 2023, after approval by a multidisciplinary committee in two French hospitals. CAB and LEN were started on the same day: oral loading dose of LEN 600 mg on day 1 and day 2, and subcutaneous LEN 927 mg on day 1 and then every 6 months, in combination with intramuscular CAB 600 mg on day 1, week 4, and then every 8 weeks. Antiretroviral plasma concentrations (Cpl) were routinely determined by UPLC-MS/MS at each visit.

Results: Patients were four women and four men; median age (IQR 25–75) 56 years (44–58); duration from ART initiation 25 years (18–32); duration of viral suppression 32 months (7–59); four had CD4 counts below 200/mm3. All had difficulty accepting their illness and had adherence problems. All patients were monitored for at least 6 months, and three for 12 months, with a median of 3 pVL measurements per patient (range 1–4). No virological failures were observed during follow-up, as all pVL remained below 50 copies/ml. No serious adverse events or discontinuations were reported. All LEN trough Cpl were >15.5 ng/ml (4xPA-IC95 in MT-4 cells) and median (IQR 25–75) CAB Cpl was 1829 ng/ml (1483–2166) approximately 58 days after the last intramuscular injection. Despite the expected moderate injection site reactions, all patients expressed a preference for this treatment over oral ART.

Conclusions: CAB plus LEN maintained effective viral suppression with good tolerability. It holds great promise for vulnerable PLWH struggling with oral ART adherence, particularly when RPV is not an option anymore, and merits prospective evaluation in a large, randomized trial.

Capsid inhibition with lenacapavir in HIV-1 infection: real-life results from the French compassionate use program. **IAS2025**, Abstract No. EP0195; **C. Delaugerre,** S. Mafi, A. Zenuni, K. Amat, S. Seang, C. Duvivier, D. Chirio, J.-P. Viard, L. Hocqueloux, E. Estrabaud, G. Peytavin, J. Ghosn, C. Charpentier, R. Landman, L. Assoumou, K. Lacombe

BACKGROUND: Lenacapavir is a first-in-class capsid inhibitor that showed substantial antiviral activity in a phase 3 study among participants with multidrug-resistant HIV-1. We aimed to evaluate the efficacy and safety of lenacapavir with an optimised background regimen (OBR) received through the compassionate access in France. **METHODS:** Participants with previous multidrug failure were prospectively enrolled between January 1st, 2021 and December 31st, 2023. Following a 2-week oral lenacapavir, they received subcutaneous lenacapavir every W26 with an OBR. A retrospective efficacy analysis was performed with the primary end point as the percentage of participants with HIV-1 viral load (VL) < 50copies/ml at W26. Secondary endpoints were virological outcomes at end of follow up, emergence of lenacapavir resistance in case of virological failure and tolerance.**RESULTS:** Thirty-three participants (11/33 females) were analysed with a median (IQR) age of 56 (41-59) years. At lenacapavir initiation, median CD4 cells count was 330 (106-500) cells/µL with 11/27 (41%) participants having less than 200 cells per µL. VL was 2.54 (1.48-4.27) log10 copies/ml with 14/33 (42%) having VL below 50 copies/ml. OBR included mainly darunavir/r (n=13), dolutegravir (n=11), cabotegravir (n=10), fostemsavir (n=12), maraviroc (n=8), ibalizumab (n=7) and enfuvirtide (n=4). At W26 (W22 to W30), a VL < 50 copies/ml was reported in 66.7% (CI95% 48.2-82.0) of the participants with a mean increase in the CD4+ count of +92 cells/µL.HIV-1 capside sequencing was performed in 7 participants with virological failure and the Q67H mutation conferring resistance to lenacapavir was evidenced in one case. There were no grade 3 or 4 treatment-related adverse events (included two deaths). Injection site reactions were reported for 11/33 (33%) participants without treatment discontinuation. **CONCLUSIONS:** In this real-life cohort of highly treatment-experienced HIV-1 participants, lenacapavir in combination with an OBR resulted in a high level of virological suppression up to 26 weeks, even increasing throughout the end of follow-up.

Additional documents

No documents were uploaded

Useful links

- Lenacapavir plus Cabotegravir real-world use cases from the National Clinician Consultation Center (EP0190 - IAS2025)
- Rapport d'activité IMEA
- Long acting cabotegravir plus lenacapavir as a fully injectable maintenance antiretroviral regimen in people with HIV with adherence issues, Glasgow 2024 , Palich R. et al
- LAI CAB/RPV plus SC LEN Effective in PWH with Poor Long-term Adherence and INSTI or NNRTI RAMs, IDWeek2024, Brock J. et al
- Eldib J, et al. Dual LA-ART in HIV-MDR Case Series. Presented at Fast-Track Cities, October 13-15, 2024, Paris, France. Poster
- Lenacapavir plus Cabotegravir real-world use cases from the National Clinician Consultation Center-IAS2025 Kigali- EP0190
- Long-acting ART (LEN/CAB and CAB/RPV) among viremic persons living with HIV - Chaudhuri et al - IAS2025-EP0199

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