Cabotegravir and Rilpivirine
Originator/manufacturer

ViiV Healthcare
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.

Janssen Pharmaceuticals
https://www.janssen.com/
Belgium

Janssen Pharmaceuticals is a subsidiary company of Johnson & Johnson headquartered in Beerse, Belgium. They manufacture and develop pharmaceutical products for use in areas such as, Immunology, Infectious Diseases & Vaccines, Pulmonary Hypertension, Cardiovascular & Metabolism, Oncology, and Neuroscience.
Drug structure

Cabotegravir Chemical Structure

Sourced from DrugBank
Rilpivirine Chemical Structure
Sourced from DrugBank

CAB/RPV Chemical Structures
Constituent Images Sourced from DrugBank
Drug information

Associated long-acting platforms
Aqueous drug particle suspension

Administration route
Oral, Subcutaneous, Intramuscular

Therapeutic area(s)
HIV

Use case(s)
Treatment

Use of drug

Ease of administration
Administered by a nurse
Administered by a specialty health worker
Self-administered

User acceptance
Not provided
Drug information

Drug's link(s)
Not provided

Generic name
Cabotegravir and Rilpivirine

Brand name
Cabenuva (Cabotegravir and Rilpivirine co-packaged medication) and Vocabria (Cabotegravir) co-administered with Rekambys (Rilpivirine).

Summary
Long-acting injectable Cabotegravir and Rilpivirine (CAB/RPV-LA) is a complete treatment regimen for HIV-1 infection consisting of two components: (1) Cabotegravir a HIV-1 integrase strand transfer inhibitor developed by ViiV Healthcare and (2) Rilpivirine a second-generation non-nucleoside reverse transcriptase inhibitor manufactured by Janssen. CAB/RPV-LA is designated for the treatment of HIV-1 infection in virologically suppressed (<50 copies/mL HIV-1 RNA) adults and adolescents aged twelve and over who weigh at least 77 pounds (35 kilograms) receiving a stable antiretroviral regimen with no history of treatment failure or resistance to either rilpivirine and/or cabotegravir.

Approval status
Cabotegravir and Rilpivirine extended-release injectable suspensions co-packaged as CABENUVA is approved by the USFDA, Health Canada, Australia, UAE and UK. Individually packaged extended-release Cabotegravir (VOCABRIA) and extended-release Rilpivirine (REKAMBYS) are approved in the Argentina, European Union, Botswana, Brazil, Canada, Chile, China, Hong Kong, Israel, Japan, Russia, Singapore, South Africa, South Korea, Taiwan, UAE, and UK for co-administration in the treatment
of HIV-1 infection. CAB- RPV LA injectables are awaiting approval in countries such as Colombia, Mexico and Thailand.

**Regulatory authorities**

CAB and RPV combination has received supplemental NDA approval with an Extended Label from the USFDA, inclusion in the Black Triangle Symbol Scheme by TGA Australia, and European Marketing Authorization by the EMA. This combination is specifically indicated for virologically suppressed adults with HIV-1 infection (HIV-1 RNA <50 copies per millilitre [c/ml]), weighing at least 35 kg. Eligible patients must have previously maintained stability on a treatment regimen without experiencing treatment failure or showing signs of resistance to Rilpivirine/Cabotegravir.

**Delivery device(s)**

No delivery device
Scale-up and manufacturing prospects

Scale-up prospects

Compounds are commercially manufactured.

Tentative equipment list for manufacturing

Conventional wet-bead milling apparatus (e.g. Netzsch ball mill), depyrogenated glass vials, high pressure homogenizer.

Manufacturing

Cabotegravir and Rilpivirine are formulated into a wet-mill suspension of approximately 200mg/ml and 300mg/ml respectively, due to their low aqueous solubility. This formulation results in the creation of nanocrystal drug particles which are amenable for intramuscular gluteal depot injection. The manufacturing process for RPV is considered to be non-standard due to the inclusion of an aseptic processing step. RPV is light-sensitive, and exposure to light can induce conversion into a Z-isomer form which can affect pharmacokinetic data and activity.

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), Mettler TGA/DSC 1 instrument for thermal analysis, Laser diffractor (determine particle size), FT-IR UHPLC (chemical identification), UHPLC (chromatographic purity), paddle apparatus & UPLC/UV (determine in-vitro drug release for QC / dissolution testing).
Clinical trials

POLAR

Identifier
NCT03639311

Link
https://clinicaltrials.gov/study/NCT03639311

Phase
Phase II

Status
Completed

Sponsor
ViiV Healthcare

More details
Not provided

Purpose
Assess the antiviral activity and safety of CAB LA plus RPV LA, administered Q2M, in approximately 100 adult HIV-1 infected, antiretroviral therapy (ART) experienced participants.

Interventions
Drug: CAB LA
Drug: RPV LA
Drug: RPV
Drug: DTG

Countries
United States of America
Canada

Sites / Institutions
Not provided

Trials dates
Anticipated Start Date
Not provided

Actual Start Date
2018-08-20

Anticipated Date of Last Follow-up
Not provided

Estimated Primary Completion Date
Not provided

Estimated Completion Date
Not provided

Actual Primary Completion Date
2019-12-11

Actual Completion Date
2023-01-30

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**

Participants will rollover from the NCT01641809 (LATTE) study, who have completed minimum duration of Week 312 and with demonstrated HIV-1 ribonucleic acid (RNA) suppression (less than \(<\)50 copies (c) per milliliter [mL]), while receiving a two-drug regimen consisting of once-daily oral CAB at 30 milligram (mg) plus RPV at 25 mg. The participants will be offered the option to switch to the LA, intramuscular injections of CAB LA plus RPV LA, Q2M or the oral fixed dose combination (FDC) of dolutegravir (DTG) plus RPV, for the continued maintenance of HIV-1 RNA suppression, known as the Maintenance Phase (From Day 1 to Commercial Approval).

**Health status**

Positive to: HIV
Negative to: HBV

**Study type**

Interventional (clinical trial)

**Enrollment**
Allocation
Non-randomized

Intervention model
Parallel Assignment

Intervention model description
This is an Intervention Model, with parallel assignment, where the primary purpose of the study is treatment, with 2 arms and no masking.

Masking
Open label

Masking description
This is an open-label study, thus no masking.

Frequency of administration
Once every 8 weeks

Studied LA-formulation(s)
Injectable

Studied route(s) of administration
Intramuscular

Use case
Treatment

Key results
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<td><a href="https://doi.org/10.1097/qad.0000000000003085">https://doi.org/10.1097/qad.0000000000003085</a></td>
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Identifier
NCT04001803

Link
https://clinicaltrials.gov/study/NCT04001803

Phase
Phase III

Status
Completed

Sponsor
ViiV Healthcare

More details
Not provided

Purpose
Identify and Evaluate Strategies for Successful Implementation of the Cabotegravir + Rilpivirine Long-acting Injectable Regimen in the US.

Interventions
Drug: CAB LA+RPV LA

Countries
United States of America
Sites / Institutions
Not provided

Trials dates

Anticipated Start Date
Not provided

Actual Start Date
2019-07-08

Anticipated Date of Last Follow-up
Not provided

Estimated Primary Completion Date
Not provided

Estimated Completion Date
Not provided

Actual Primary Completion Date
2020-10-05

Actual Completion Date
2022-03-18

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
Not provided

Health status
Positive to: HIV
Negative to: HBV

Study type
Interventional (clinical trial)

Enrollment
115

Allocation
Not provided

Intervention model
Single group assignment

Intervention model description
Not provided

Masking
Open label
Masking description
None (Open Label)

Frequency of administration
Monthly

Studied LA-formulation(s)
Injectable

Studied route(s) of administration
Intramuscular

Use case
Treatment

Key results

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CR109089

Identifier
NCT05112939

Link
https://clinicaltrials.gov/study/NCT05112939

Phase
Phase I

Status
Active, not recruiting

Sponsor
Janssen Research & Development, LLC

More details
Not provided

Purpose
Characterize the single dose pharmacokinetics and evaluate the safety and tolerability of subcutaneous administration of RPV LA in combination with CAB LA in different conditions in healthy adults.

Interventions
Drug: RPV LA
Drug: CAB LA

Countries
United States of America
Netherlands

Sites / Institutions
Not provided

Trials dates

Anticipated Start Date
Not provided

Actual Start Date
2021-11-16

Anticipated Date of Last Follow-up
Not provided

Estimated Primary Completion Date
2024-05-23

Estimated Completion Date
2024-05-23

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
Unspecified

Accepts healthy individuals
Yes

Comments about the studied populations
Participant must be healthy on the basis of physical examination, clinical laboratory tests, medical history, vital signs, and 12-lead electrocardiogram (ECG).

Health status
Not provided

Study type
Interventional (clinical trial)

Enrollment
126

Allocation
Randomized

Intervention model
Parallel Assignment

Intervention model description
Not provided

Masking
Single blind masking

Masking description

Single (Participant)

Frequency of administration

Other(s) : "Single dose."

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Subcutaneous

Use case

Treatment

Key results

Not provided
ATLAS-2M

Identifier
NCT03299049

Link
https://clinicaltrials.gov/study/NCT03299049

Phase
Phase III

Status
Active, not recruiting

Sponsor
ViiV Healthcare

More details
Not provided

Purpose

Interventions
Drug: Cabotegravir Tablets
Drug: Rilpivirine Tablets
Drug: Cabotegravir Injectable Suspension
Drug: Rilpivirine Injectable Suspension
Countries

United States of America
Argentina
Australia
Canada
France
Germany
Italy
Korea, Republic of
Mexico
Russian Federation
South Africa
Spain
Sweden

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date
Not provided

Actual Start Date
2017-10-27

Anticipated Date of Last Follow-up
Not provided

Estimated Primary Completion Date
Not provided

Estimated Completion Date
2026-12-31
Actual Primary Completion Date
2019-06-06

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
Not provided

Health status

Positive to : HIV
Negative to : HBV

Study type

Interventional (clinical trial)
Enrollment
1049

Allocation
Randomized

Intervention model
Parallel Assignment

Intervention model description
Two groups of subjects will be randomized to receive CAB LA + RPV LA Q4W, or CAB LA + RPV LA Q8W regimen.

Masking
Open label

Masking description
This will be an open-label study and therefore no blinding is required.

Frequency of administration
Monthly
Once every 8 weeks

Studied LA-formulation(s)
Injectable

Studied route(s) of administration
Intramuscular

Use case
## Key results

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<td>Patient-Reported Outcomes Through 1 Year of an HIV-1 Clinical Trial Evaluating Long-Acting Cabotegravir and Rilpivirine Administered Every 4 or 8 Weeks (ATLAS-2M)</td>
<td><a href="https://doi.org/10.1007/s40271-021-00524-0">https://doi.org/10.1007/s40271-021-00524-0</a></td>
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**SOLAR**

**Identifier**
NCT04542070

**Link**
https://clinicaltrials.gov/study/NCT04542070

**Phase**
Phase III

**Status**
Completed

**Sponsor**
ViiV Healthcare

**More details**
Not provided

**Purpose**
Assess the antiviral activity and safety of a two-drug regimen of CAB LA + RPV LA compared with maintenance of BIK. BIKTARVY is a registered trademark of Gilead Sciences.

**Interventions**
- Drug: Cabotegravir Tablets
- Drug: Cabotegravir Injectable Suspension (CAB LA)
- Drug: Rilpivirine Tablets
- Drug: Rilpivirine Injectable Suspension (RPV LA)
Drug: BIKTARVY Tablets (BIK)

**Countries**

United States of America
Australia
Austria
Belgium
Canada
France
Germany
Ireland
Italy
Japan
Netherlands
Spain
Switzerland
United Kingdom

**Sites / Institutions**

Not provided

**Trials dates**

**Anticipated Start Date**
Not provided

**Actual Start Date**
2020-11-09

**Anticipated Date of Last Follow-up**
Not provided

**Estimated Primary Completion Date**
Not provided
Estimated Completion Date
Not provided

Actual Primary Completion Date
2022-07-13

Actual Completion Date
2023-04-17

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
Not provided

Health status
Positive to : HIV
Negative to : HBV

Study type
Interventional (clinical trial)

Enrollment
687

Allocation
Randomized

Intervention model
Parallel Assignment

Intervention model description
Not provided

Masking
Open label

Masking description
None (Open Label)

Frequency of administration
Once every 8 weeks

Studied LA-formulation(s)
Injectable

Studied route(s) of administration
Intramuscular

Use case
Treatment
# Key results

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<td><a href="https://doi.org/10.1089/apc.2022.0168">https://doi.org/10.1089/apc.2022.0168</a></td>
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ATLAS

Identifier
NCT02951052

Link
https://clinicaltrials.gov/study/NCT02951052

Phase
Phase III

Status
Active, not recruiting

Sponsor
ViiV Healthcare

More details
Not provided

Purpose
Establish if HIV-1 infected adult subjects with current viral suppression on a regimen with 2 NRTIs plus a third agent, remain suppressed upon switching to a 2 drug intramuscular regime of CAB/RPV-LA.

Interventions
Drug: Cabotegravir (CAB) tablets
Drug: Rilpivirine (RPV) tablets
Drug: Cabotegravir - Injectable Suspension (CAB LA)
Drug: Rilpivirine - Injectable Suspension (RPV LA)
Drug: 2 NRTIs plus an INI, NNRTI, or PI

Countries

United States of America
Argentina
Australia
Canada
France
Germany
Italy
Korea, Republic of
Mexico
Russian Federation
South Africa
Spain
Sweden

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date
Not provided

Actual Start Date
2016-10-28

Anticipated Date of Last Follow-up
Not provided

Estimated Primary Completion Date
Not provided

Estimated Completion Date
Actual Primary Completion Date
2018-05-29

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
Must be on uninterrupted current ARV regimen (either the initial or second ARV regimen) for at least 6 months prior to Screening. Any prior switch, defined as a change of a single drug or multiple drugs simultaneously, must have occurred due to tolerability/safety, access to medications, or convenience/simplification, and must NOT have been done for treatment failure (HIV-1 RNA ≥400 c/mL).

Health status
Positive to : HIV
Negative to: HBV

**Study type**

Interventional (clinical trial)

**Enrollment**

618

**Allocation**

Randomized

**Intervention model**

Parallel Assignment

**Intervention model description**

Not provided

**Masking**

Open label

**Masking description**

None (Open Label)

**Frequency of administration**

Monthly

**Studied LA-formulation(s)**

Injectable

**Studied route(s) of administration**

Intramuscular
## Use case

**Treatment**

## Key results

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**FLAIR**

**Identifier**
NCT02938520

**Link**
https://clinicaltrials.gov/study/NCT02938520

**Phase**
Phase III

**Status**
Active, not recruiting

**Sponsor**
ViiV Healthcare

**More details**
Not provided

**Purpose**
Establish if HIV-1 infected adult participants whose virus is virologically suppressed on an INI STR will remain suppressed after switching to a two drug LA regimen of CAB and RPV.

**Interventions**
- Drug: Cabotegravir (CAB) tablets
- Drug: Rilpivirine (RPV) tablets
- Drug: Cabotegravir - Injectable Suspension (CAB LA)
- Drug: Rilpivirine - Injectable Suspension (RPV LA)
Drug: Oral ABC/DTG/3TC STR Tablet & Drug: Oral DTG Tablet

Countries

United States of America
Canada
France
Germany
Italy
Japan
Netherlands
Russian Federation
South Africa
Spain
United Kingdom

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date
Not provided

Actual Start Date
2016-10-27

Anticipated Date of Last Follow-up
Not provided

Estimated Primary Completion Date
Not provided

Estimated Completion Date
2026-12-31

Actual Primary Completion Date
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
Antiretroviral-naive (<=10 days of prior therapy with any antiretroviral agent following a diagnosis of HIV-1 infection). Any previous exposure to an HIV integrase inhibitor or non-nucleoside reverse transcriptase inhibitor will be exclusionary.

Health status
Negative to: HBV
Positive to: HIV

Study type
Interventional (clinical trial)
Enrollment
631

Allocation
Randomized

Intervention model
Parallel Assignment

Intervention model description
Not provided

Masking
Open label

Masking description
None (Open Label)

Frequency of administration
Monthly

Studied LA-formulation(s)
Injectable

Studied route(s) of administration
Intramuscular

Use case
Treatment

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CARISEL

Identifier
NCT04399551

Link
https://clinicaltrials.gov/study/NCT04399551

Phase
Phase III

Status
Completed

Sponsor
ViiV Healthcare

More details
Not provided

Purpose
Evaluating Implementation Strategies for Cabotegravir (CAB)+ Rilpivirine (RPV) Long-acting (LA)Injectables for Human Immunodeficiency Virus (HIV)-1 Treatment in European Countries

Interventions
Drug: Cabotegravir tablets (Oral lead-in)
Drug: Rilpivirine tablets (Oral lead-in)
Drug: CAB LA
Drug: RPV LA
Other: Continuous Quality Improvement (CQI) calls

**Countries**

Belgium  
France  
Germany  
Netherlands  
Spain

**Sites / Institutions**

Not provided

**Trials dates**

**Anticipated Start Date**  
Not provided

**Actual Start Date**  
2020-09-28

**Anticipated Date of Last Follow-up**  
Not provided

**Estimated Primary Completion Date**  
Not provided

**Estimated Completion Date**  
Not provided

**Actual Primary Completion Date**  
2022-03-07

**Actual Completion Date**  
2023-03-13

**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

HIV-1 infected and must be suppressed on a guideline recommended active Highly active antiretroviral therapy (HAART) regimen for at least 6 months prior to screening. Any prior switch, defined as a change of a single drug or multiple drugs simultaneously, must have occurred due to tolerability/safety, access to medications, or convenience/simplification, and must not have been done for virologic failure (on treatment HIV-1 RNA more than or equal to \([>=]200\text{ c/mL}\)).

Health status

Positive to : HIV
Negative to : HBV, COVID 19

Study type

Interventional (clinical trial)

Enrollment
Allocation
Non-randomized

Intervention model
Parallel Assignment

Intervention model description
Not provided

Masking
Open label

Masking description
This is an open-label study hence no blinding is required.

Frequency of administration
Monthly
Once every 8 weeks

Studied LA-formulation(s)
Injectable

Studied route(s) of administration
Intramuscular

Use case
Treatment

Key results
<table>
<thead>
<tr>
<th>Type of key results</th>
<th>Title</th>
<th>Website link</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abstract</td>
<td>Top Practices for Implementing Cabotegravir (CAB) and Rilpivirine (RPV) Long-Acting (LA) in European Clinics</td>
<td><a href="https://www.bhiva.org/file/62a1ceca806">https://www.bhiva.org/file/62a1ceca806</a></td>
</tr>
</tbody>
</table>
LATA

Identifier
NCT05154747

Link
https://clinicaltrials.gov/study/NCT05154747

Phase
Phase III

Status
Active, not recruiting

Sponsor
University College, London

More details
Not provided

Purpose
Comparing the efficacy of long-acting injectable CAB+RPV administered every two months in comparison to daily oral HIV medications in young people.

Interventions
Drug: Cabotegravir, Rilpivirine Drug Combination
Drug: TLD

Countries
Kenya
South Africa
Uganda
Zimbabwe

Sites / Institutions
Not provided

Trials dates

Anticipated Start Date
Not provided

Actual Start Date
2023-06-22

Anticipated Date of Last Follow-up
Not provided

Estimated Primary Completion Date
2025-03-01

Estimated Completion Date
2026-03-01

Actual Primary Completion Date
Not provided

Actual Completion Date
Not provided

Studied populations

Age Cohort

- Children
- Adolescents
- Adults
Genders

- All

Accepts pregnant individuals
No

Accepts lactating individuals
No

Accepts healthy individuals
No

Comments about the studied populations

Study participants are individuals with HIV-1 infection aged 12-19 years in Sub-Saharan Africa. Participants with known HIV-2 infection are excluded.

Health status

Positive to: HIV
Negative to: HBV

Study type

Interventional (clinical trial)

Enrollment

476

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description
Masking

Open label

Masking description

None (Open Label)

Frequency of administration

Once every 8 weeks

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

Treatment

Key results

Not provided
IMPALA

Identifier
NCT05546242

Link
https://clinicaltrials.gov/study/NCT05546242

Phase
Phase III

Status
Recruiting

Sponsor
MRC/UVRI and LSHTM Uganda Research Unit

More details
Not provided

Purpose
Evaluating the Effectiveness of Switching to Two-monthly Long-acting Injectable CAB and RPV From First-line Oral Antiretroviral Therapy in HIV-1 Positive Virologically Suppressed Adults in SSA.

Interventions
Drug: Long-acting injectable Cabotegravir/Rilpivirine
Drug: Antiretroviral

Countries
Uganda
Kenya
South Africa

Sites / Institutions
Not provided

Trials dates

Anticipated Start Date
Not provided

Actual Start Date
2022-12-08

Anticipated Date of Last Follow-up
Not provided

Estimated Primary Completion Date
2024-11-01

Estimated Completion Date
2025-11-01

Actual Primary Completion Date
Not provided

Actual Completion Date
Not provided

Studied populations

Age Cohort

- Adults
- Older Adults

Genders
Accepts pregnant individuals
No

Accepts lactating individuals
No

Accepts healthy individuals
No

Comments about the studied populations

Participants must have a history of sub-optimal ART adherence or engagement in care based on one or more of the following criteria: 1. Documented detectable HIV-1 VL (>1000 c/mL) on all-oral ART (EFV/NVP or DTG-based) in the prior 2 years despite being ART-experienced for ≥3 months. 2. History of being lost to follow-up from care (>4 weeks elapsed since a missed scheduled clinic appointment or refill in the prior 2 years). 3. Failed to link to HIV care despite ≥3 months elapsed since HIV diagnosis.

Health status

Positive to : HIV
Negative to : HBV, TB

Study type

Interventional (clinical trial)

Enrollment

540

Allocation

Randomized

Intervention model
Parallel Assignment

**Intervention model description**

Parallel open-label phase 3b study. Participants will be randomised to continuing current therapy or switching to injectable therapy.

**Masking**

Open label

**Masking description**

None (Open Label)

**Frequency of administration**

Once every 8 weeks

**Studied LA-formulation(s)**

Injectable

**Studied route(s) of administration**

Intramuscular

**Use case**

Treatment

**Key results**

Not provided
LATITUDE

Identifier

NCT03635788

Link

https://clinicaltrials.gov/study/NCT03635788

Phase

Phase III

Status

Recruiting

Sponsor

National Institute of Allergy and Infectious Diseases (NIAID)

More details

Not provided

Purpose

Compare the efficacy, safety, and durability of two different strategies to treat participants with a history of sub-optimal adherence and control of their HIV infection.

Interventions

Drug: Standard of Care (SOC) Oral ART
Drug: Oral Rilpivirine tablets
Drug: Oral Cabotegravir tablets
Drug: Injectable RPV-LA
Drug: Injectable CAB-LA
Countries

United States of America
Puerto Rico

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date
Not provided

Actual Start Date
2019-03-28

Anticipated Date of Last Follow-up
Not provided

Estimated Primary Completion Date
2025-06-30

Estimated Completion Date
2026-12-31

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

Evidence of non-adherence to ART according to at least one of the following criteria: 1. Poor virologic response within 18 months prior to study entry (defined as less than 1 log10 decrease in HIV-1 RNA or HIV-1 RNA greater than 200 copies/mL at two time points at least 4 weeks apart) in individuals who have been prescribed ART for at least 6 consecutive months. 2. Lost to clinical follow-up within 18 months prior to study entry with ART non-adherence for greater than or equal to 6 consecutive months.

Health status

Positive to: HIV
Negative to: HBV

Study type

Interventional (clinical trial)

Enrollment

350

Allocation

Randomized
Intervention model
Parallel Assignment

Intervention model description
Not provided

Masking
Open label

Masking description
None (Open Label)

Frequency of administration
Monthly

Studied LA-formulation(s)
Injectable

Studied route(s) of administration
Intramuscular

Use case
Treatment

Key results
Not provided
**LATTE-2**

**Identifier**
NCT02120352

**Link**
https://clinicaltrials.gov/study/NCT02120352

**Phase**
Phase II

**Status**
Completed

**Sponsor**
ViiV Healthcare

**More details**
Not provided

**Purpose**
Evaluate the antiviral activity, tolerability, and safety of IM dosing regimens of GSK744 LA plus TMC278 LA, relative to GSK744 plus ABC/3TC given orally once daily, in ARV naïve HIV-1 patients.

**Interventions**
- Drug: Oral GSK744 tablets
- Drug: Injectable GSK744 LA
- Drug: Injectable TMC278 LA
- Drug: Oral ABC/3TC tablets
Drug: Oral RPV tablets

**Countries**

United States of America
Canada
France
Germany
Spain

**Sites / Institutions**

Not provided

**Trials dates**

**Anticipated Start Date**
Not provided

**Actual Start Date**
2014-04-28

**Anticipated Date of Last Follow-up**
Not provided

**Estimated Primary Completion Date**
Not provided

**Estimated Completion Date**
Not provided

**Actual Primary Completion Date**
2015-08-13

**Actual Completion Date**
2023-04-20

**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

Participants must be ART-naïve defined as having no more than 10 days of prior therapy with any antiretroviral agent following a diagnosis of HIV-1 infection.

Health status

Positive to : HIV
Negative to : HBV

Study type

Interventional (clinical trial)

Enrollment

309

Allocation

Randomized
Intervention model
Parallel Assignment

Intervention model description
Not provided

Masking
Open label

Masking description
None (Open Label)

Frequency of administration
Monthly
Once every 8 weeks

Studied LA-formulation(s)
Injectable

Studied route(s) of administration
Intramuscular

Use case
Treatment

Key results

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<tbody>
<tr>
<td>Article</td>
<td>URL</td>
<td></td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Experiences with long acting injectable ART: A qualitative study among PLHIV participating in a Phase II study of cabotegravir + rilpivirine (LATTE-2) in the United States and Spain.</td>
<td><a href="https://doi.org/10.1371/journal.pone.0190487">https://doi.org/10.1371/journal.pone.0190487</a></td>
<td></td>
</tr>
<tr>
<td>Efficacy, Safety, and Durability of Long-Acting Cabotegravir and Rilpivirine in Adults With Human Immunodeficiency Virus Type 1 Infection: 5-Year Results From the LATTE-2 Study.</td>
<td><a href="https://doi.org/10.1093/ofid/ofab439">https://doi.org/10.1093/ofid/ofab439</a></td>
<td></td>
</tr>
<tr>
<td>Pharmacokinetics and antiviral activity of cabotegravir and rilpivirine in cerebrospinal fluid following long-acting injectable administration in HIV-infected adults.</td>
<td><a href="https://doi.org/10.1093/jac/dkz504">https://doi.org/10.1093/jac/dkz504</a></td>
<td></td>
</tr>
<tr>
<td>Patient-reported tolerability and acceptability of cabotegravir + rilpivirine long-acting injections for the treatment of HIV-1 infection: 96-week results from the randomized LATTE-2 study.</td>
<td><a href="https://doi.org/10.1080/25787489.2019.1661696">https://doi.org/10.1080/25787489.2019.1661696</a></td>
<td></td>
</tr>
<tr>
<td>Long-acting intramuscular cabotegravir and rilpivirine in adults with HIV-1 infection (LATTE-2): 96-week results of a randomised, open-label, phase 2b, non-inferiority trial.</td>
<td><a href="https://doi.org/10.1016/s0140-6736(17)31917-7">https://doi.org/10.1016/s0140-6736(17)31917-7</a></td>
<td></td>
</tr>
</tbody>
</table>
NCT04371380

Identifier

NCT04371380

Link

https://clinicaltrials.gov/study/NCT04371380

Phase

Phase I

Status

Completed

Sponsor

ViiV Healthcare

More details

Not provided

Purpose

Evaluate pharmacokinetics, tolerability, and safety of Cabotegravir long acting plus Rilpivirine long acting administered concomitantly as two separate IM injections in the Vastus Lateralis muscles.

Interventions

Drug: Oral Cabotegravir Tablets
Drug: Oral Rilpivirine Tablets
Drug: Cabotegravir extended release suspension for injection (long-acting)
Drug: Rilpivirine extended release suspension for injection (long-acting)
Countries
United States of America

Sites / Institutions
Not provided

Trials dates

Anticipated Start Date
Not provided

Actual Start Date
2020-09-16

Anticipated Date of Last Follow-up
Not provided

Estimated Primary Completion Date
Not provided

Estimated Completion Date
Not provided

Actual Primary Completion Date
2021-12-26

Actual Completion Date
2021-12-26

Studied populations

Age Cohort
- Adults

Genders
- All
Accepts pregnant individuals
No

Accepts lactating individuals
No

Accepts healthy individuals
Yes

Comments about the studied populations
Participants aged 18 to 50 who are overtly healthy as determined by medical evaluation including medical history, physical examination, laboratory tests, and cardiac monitoring.

Health status
Negative to: HIV, HCV, HBV, COVID 19

Study type
Interventional (clinical trial)

Enrollment
15

Allocation
Not provided

Intervention model
Single group assignment

Intervention model description
Eligible participants will receive orally, tablets of cabotegravir plus rilpivirine for 28 days. There will be 10 to 14 days wash out period followed by an IM injection of
cabotegravir long-acting plus rilpivirine long-acting.

**Masking**

Open label

**Masking description**

This is an open label study.

**Frequency of administration**

Other(s) : "Single dose of CAB LA plus RPV LA."

**Studied LA-formulation(s)**

Injectable

**Studied route(s) of administration**

Intramuscular

**Use case**

Treatment

**Key results**

<table>
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<td>Abstract</td>
<td>Pharmacokinetics and Tolerability of Cabotegravir and Rilpivirine Long-Acting Intramuscular Injections to the Vastus Lateralis (Lateral Thigh) Muscles of Healthy Adult Participants.</td>
<td><a href="https://medinfo.gsk.com/5f95dbd7-245e-4e65-9f36-1a99e28e5bba/75cb786a-98e0-4615-8258-3cae0bdcfb29/75cb786a-98e0-4615-8258-3cae0bdcfb29_viewable_rendition_v.pdf">https://medinfo.gsk.com/5f95dbd7-245e-4e65-9f36-1a99e28e5bba/75cb786a-98e0-4615-8258-3cae0bdcfb29/75cb786a-98e0-4615-8258-3cae0bdcfb29_viewable_rendition_v.pdf</a></td>
</tr>
</tbody>
</table>
LAI115428

Identifier
NCT01593046

Link
https://clinicaltrials.gov/study/NCT01593046

Phase
Phase I

Status
Completed

Sponsor
ViiV Healthcare

More details
Not provided

Purpose
Investigate the Safety, Tolerability and Pharmacokinetics of Repeat Dose Administration of Long-Acting GSK1265744 and Long-Acting TMC278 Intramuscular and Subcutaneous Injections.

Interventions
Drug: Oral GSK1265744 tablets
Drug: Injectable Intramuscular GSK1265744 LA
Drug: Injectable Subcutaneous GSK1265744 LA
Drug: Injectable Intramuscular TMC278 LA
Countries
United States of America

Sites / Institutions
Not provided

Trials dates

Anticipated Start Date
Not provided

Actual Start Date
2012-05-01

Anticipated Date of Last Follow-up
Not provided

Estimated Primary Completion Date
Not provided

Estimated Completion Date
Not provided

Actual Primary Completion Date
2013-11-01

Actual Completion Date
2013-11-01

Studied populations

Age Cohort
- Adults

Genders
- All
Accepts pregnant individuals
No

Accepts lactating individuals
Unspecified

Accepts healthy individuals
Yes

Comments about the studied populations
Not provided

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

Study type
Interventional (clinical trial)

Enrollment
43

Allocation
Randomized

Intervention model
Parallel Assignment

Intervention model description
Not provided

Masking
Open label

Masking description
None (Open Label)

Frequency of administration
Monthly

Studied LA-formulation(s)
Injectable

Studied route(s) of administration
Intramuscular

Use case
Unspecified

Key results
Not provided
CAPRI

Identifier
NCT05601128

Link
https://clinicaltrials.gov/study/NCT05601128

Phase
Phase III

Status
Active, not recruiting

Sponsor
Allegheny Singer Research Institute

More details
Not provided

Purpose
Evaluate the efficacy and safety of CABENUVA (Long-acting Cabotegravir Plus Long-acting Rilpivirine) in patients with HIV infection and severe renal impairment.

Interventions
Drug: Injectable CAB LA + RPV LA

Countries
Not provided
Sites / Institutions

Not provided

Trials dates

Anticipated Start Date
Not provided

Actual Start Date
2023-01-01

Anticipated Date of Last Follow-up
Not provided

Estimated Primary Completion Date
2024-12-31

Estimated Completion Date
2025-12-31

Actual Primary Completion Date
Not provided

Actual Completion Date
Not provided

Studied populations

Age Cohort
- Adults
- Older Adults

Genders
- All

Accepts pregnant individuals
Accepts lactating individuals
No

Accepts healthy individuals
No

Comments about the studied populations
Participants are positive for HIV infection and severe renal impairment with or without hemodialysis.

Health status
Positive to : HIV
Negative to : HBV

Study type
Interventional (clinical trial)

Enrollment
12

Allocation
Not provided

Intervention model
Single group assignment

Intervention model description
Not provided

Masking
Open label

**Masking description**

None (Open Label)

**Frequency of administration**

Monthly
Once every 8 weeks

**Studied LA-formulation(s)**

Injectable

**Studied route(s) of administration**

Intramuscular

**Use case**

Treatment

**Key results**

Not provided
MOCHA

Identifier
NCT03497676

Link
https://clinicaltrials.gov/study/NCT03497676

Phase
Phase I/II

Status
Active, not recruiting

Sponsor
National Institute of Allergy and Infectious Diseases (NIAID)

More details
Not provided

Purpose
Evaluate the safety, acceptability, tolerability, and pharmacokinetics of oral and long-acting injectable CAB and RPV in virologically suppressed HIV-infected children and adolescents.

Interventions
Drug: Oral Cabotegravir (CAB)
Drug: Oral Rilpivirine (RPV)
Drug: Long-Acting Injectable Cabotegravir (CAB LA)
Drug: Long-Acting Injectable Rilpivirine (RPV LA)
Drug: Combination Antiretroviral Therapy (cART)

**Countries**

United States of America
Botswana
Puerto Rico
South Africa
Thailand
Uganda

**Sites / Institutions**

Not provided

**Trials dates**

**Anticipated Start Date**
Not provided

**Actual Start Date**
2019-03-19

**Anticipated Date of Last Follow-up**
Not provided

**Estimated Primary Completion Date**
Not provided

**Estimated Completion Date**
2025-06-17

**Actual Primary Completion Date**
2023-02-18

**Actual Completion Date**
Not provided
**Studied populations**

**Age Cohort**
- Children
- Adolescents

**Genders**
- All

**Accepts pregnant individuals**
No

**Accepts lactating individuals**
No

**Accepts healthy individuals**
No

**Comments about the studied populations**
Not provided

**Health status**
Positive to: HIV
Negative to: HCV, HBV

**Study type**
Interventional (clinical trial)

**Enrollment**
168

**Allocation**
Non-randomized
Intervention model
Sequential assignment

Intervention model description
Not provided

Masking
Open label

Masking description
None (Open Label)

Frequency of administration
Monthly
Once every 8 weeks

Studied LA-formulation(s)
Injectable

Studied route(s) of administration
Intramuscular

Use case
Treatment

Key results
Not provided
VOLITION

Identifier
NCT05917509

Link
https://clinicaltrials.gov/study/NCT05917509

Phase
Phase III

Status
Recruiting

Sponsor
ViiV Healthcare

More details
Not provided

Purpose
Evaluate the efficacy, safety, implementation effectiveness, and patient-reported outcomes of once-daily oral DTG/3TC followed by an optional participant-determined switch to CAB/RPV-LA.

Interventions
Drug: DTG/3TC
Drug: Cabotegravir (CAB) LA
Drug: Rilpivirine (RPV) LA

Countries
United States of America
Argentina
Canada
Chile
France
Germany
Italy
Puerto Rico
Spain

**Sites / Institutions**
Not provided

**Trials dates**

**Anticipated Start Date**
Not provided

**Actual Start Date**
2023-07-06

**Anticipated Date of Last Follow-up**
Not provided

**Estimated Primary Completion Date**
Not provided

**Estimated Completion Date**
2025-08-25

**Actual Primary Completion Date**
2026-01-30

**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

Antiretroviral-naïve participants (defined as no prior therapy with any antiretroviral agent following a diagnosis of HIV-1 infection) prior to enrolment with plasma HIV-1 RNA ≥1,000 c/mL at screening. Participants enrolled in France must be affiliated to, or a beneficiary of, a social security category.

Health status

Positive to: HIV
Negative to: HBV, COVID 19

Study type

Interventional (clinical trial)

Enrollment

180

Allocation
Non-randomized

**Intervention model**
Parallel Assignment

**Intervention model description**
Not provided

**Masking**
Open label

**Masking description**
None (Open Label)

**Frequency of administration**
Once every 8 weeks

**Studied LA-formulation(s)**
Injectable

**Studied route(s) of administration**
Intramuscular

**Use case**
Treatment

**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**

The novel excipient poloxamer 338 (P338) is used in the final G001 Rilpivirine clinical formulation. Following both an in-vitro mammalian chromosome aberration and an Ames test, it was considered to be non-genotoxic with no evidence for mutagenicity. Further P338 fertility, genotoxicity and development studies have been conducted with no negative effects, in addition to a 6-week and 9-month minipig repeat-dose toxicity study. No adverse local or systemic toxicity was reported in the minipigs at 100mg/month (Margin of Exposure:19).

**Residual solvents used**

No residual solvent used
There are either no relevant patents or these were not yet submitted to LAPaL
Supporting material
Publications


Purpose of review

Cabotegravir (CAB) and rilpivirine (RPV) is the first long-acting injectable antiretroviral therapy (ART) option approved for virologically suppressed adults with HIV-1. In addition, long-acting CAB is a promising agent for HIV preexposure prophylaxis (PrEP). This review focuses on phase 3 clinical trial results and implementation considerations for these long-acting ART and PrEP strategies.

Recent findings

Long-acting CAB and RPV administered every 4 weeks demonstrated noninferiority to oral ART through week 96 in both the ATLAS and FLAIR studies, whereas ATLAS-2M found similar efficacy through 96 weeks when the long-acting injectable ART was administered every 8 weeks instead of every 4 weeks. For prevention, two phase 3 trials were stopped early due to fewer incident HIV infections in participants receiving long-acting CAB every 8 weeks compared with daily oral tenofovir disoproxil fumarate–emtricitabine for PrEP. The long-acting therapies were well tolerated across all clinical trials.

Summary

Clinical trial results support the use of long-acting CAB for HIV PrEP and long-acting
CAB and RPV as a switch strategy for adults with HIV-1 who are first virologically suppressed with oral ART. Implementation challenges persist, and data are urgently needed in populations who may benefit most from long-acting therapy, including adolescents, pregnant individuals, and those with barriers to medication adherence.

Additional documents

No documents were uploaded

Useful links

- FDA Approves Cabenuva and Vocabria for the Treatment of HIV-1 Infection
- CABENUVA FDA Highlights of Prescribing Information
Not provided