An observational study evaluating long-acting injectable cabotegravir (CAB-LA; APRETUDE) healthcare provider and user experience and utilization for pre-exposure prophylaxis (PrEP) against HIV in Canada (223857)

First published: 31/10/2025

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000801

Study ID

1000000801

DARWIN EU® study

No

Study countries

Canada

Study status

Ongoing

Research institutions and networks

Institutions

ViiV Healthcare

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Institution

Broadstreet HEOR

Contact details

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Study contact

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Primary lead investigator

Call Center ViiV Healthcare UK Limited

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 03/11/2025

Actual: 01/11/2024

Study start date
Planned: 19/12/2025

Actual: 18/12/2025

Date of final study report
Planned: 15/04/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ViiV Healthcare ULC

Study protocol

HIV Apretude KAB survey and PSP analysis_Protocol_ FINAL-Anonymised.pdf

(1.88 MB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Evaluation of patient-reported outcomes

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

Non-interventional study

Main study objective:

To evaluate the effectiveness of the aRMMs for CAB-LA within Canada, among HCPs and CAB-LA users.

Study Design

Non-interventional study design

Cohort

Cross-sectional

Study drug and medical condition

Medicinal product name

APRETUDE

Study drug International non-proprietary name (INN) or common name

CABOTEGRAVIR

Anatomical Therapeutic Chemical (ATC) code

(J05AJ04) cabotegravir

cabotegravir

Medical condition to be studied

HIV infection

Population studied

Short description of the study population

The study population includes HCPs comprised of physicians, nurses, and pharmacists who prescribe or administer CAB-LA, and users of CAB-LA 16 years of age or older.

Age groups

- Adolescents (12 to < 18 years)
- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Estimated number of subjects

350

Study design details

Setting

A cross-sectional survey of HCPs prescribing/administering CAB-LA and users of CAB-LA, to be conducted from December 2025 – April 2026; and a retrospective analysis of CAB-LA user data in the APRETUDE Supports Patient Support Program database, to be conducted from July 2024 – October 2027.

Outcomes

1. Number of HCPs who have used aRMMs for CAB-LA using KAB survey.
2. Number of CAB-LA users who have used aRMMs for CAB-LA using KAB survey.
3. Number of HCPs with knowledge of key CAB-LA risk messages within the HCP-specific aRMMs using KAB survey.
4. Number of users with knowledge of key CAB-LA risk messages within the user-specific aRMMs using KAB survey.
5. HCP (prescribers') attitudes regarding the importance of selecting individuals who will adhere to the CAB-LA dosing schedule and attend follow-up visits using KAB survey.
6. HCP and user behaviors as they relate to key CAB-LA risk messages within the aRMMs using KAB surveys.
7. Description of HCPs' decision-making process regarding the choice between oral PrEP and CAB-LA using HCP surveys.
8. Descriptions of HCPs' experience implementing, prescribing, or managing CAB-LA and oral PrEP in clinical practice and among individuals eligible for PrEP, including HIV-testing using HCP surveys.
9. Description of HCPs' use of CAB-LA oral lead-in and oral bridging using HCP surveys.
10. Description of HCPs' management of pharmacokinetic (PK) tail among those who discontinue CAB-LA using HCP surveys.
11. Description of HCPs' attitudes towards CAB-LA using HCP surveys.
12. Description of CAB-LA users' demographic and clinical characteristics for the participants in the APRETUDE Supports Program database that initiated CAB-LA between.
13. Description of CAB-LA users' decision-making process regarding the choice between oral PrEP and CAB-LA.
14. Description of CAB-LA users' experience using CAB-LA.
15. Description of CAB-LA users' utilization patterns for the participants in the APRETUDE Supports Program database that initiated CAB-LA between 15-July

2024 and October 2026.

Data analysis plan

The study will primarily be descriptive, survey-based for both CAB-LA users and healthcare providers.

Summary results

Results will be presented overall for HCPs and CAB-LA users, as well as stratified by characteristics of interest at the end of the study

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s), other

Cross-sectional survey, APRETUDE Supports Patient Support Program [PSP] database.

Data sources (types)

Patient surveys

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes