C2C: COMBINE-2 for Cabotegravir+Rilpivirine LA Regimen - A Prospective Cohort Study to Monitor Effectiveness, Adherence and Resistance (215160)

First published: 26/08/2021

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Study Ongoing

Administrative details

EU PAS number

EUPAS42609

Study ID

49488

DARWIN EU® study

No

Study countries

- ☐ Belgium
- ☐ France

- [ ] Germany
- [ ] Italy
- [ ] Netherlands
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] United Kingdom

Study description

This prospective cohort study will gather real world evidence in routine clinical practice to evaluate the CAB+RPV LA regimen. The study will assess effectiveness, discontinuation, and resistance over 24-months of follow-up period in patients living with HIV.

Study status

Ongoing

Research institutions and networks

Institutions

ViiV Healthcare

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Institution

Contact details

Study institution contact

GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

Study contact

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Primary lead investigator

GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/12/2020

Actual: 02/12/2020

Study start date

Planned: 13/05/2022

Actual: 05/05/2022

Date of final study report

Planned: 30/09/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ViiV Healthcare & Janssen

Study protocol

viiv-215160-protocol-orig-redact.pdf(1.47 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

• Describe study population initiating CAB+RPV LA regimen
• Assess adherence, durability and discontinuation for individuals starting the regimen
• Assess the clinical effectiveness among individuals who initiate the regimen and had suppressed viral load at regimen initiation
• Monitor for resistance in case of virologic failure while on the regimen or after switching over the follow-up period

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Name of medicine
EDURANT 25 MG - FILM-COATED TABLET
REKAMBYS
REKAMBYS 600 MG - PROLONGED-RELEASE SUSPENSION FOR INJECTION
REKAMBYS 900 MG - PROLONGED-RELEASE SUSPENSION FOR INJECTION
VOCABRIA
VOCABRIA 30 MG - FILM-COATED TABLET
VOCABRIA 400 MG - PROLONGED-RELEASE SUSPENSION FOR INJECTION
VOCABRIA 600 MG - PROLONGED-RELEASE SUSPENSION FOR INJECTION

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

Anatomical Therapeutic Chemical (ATC) code

(J05AG05) rilpivirine

rilpivirine

(J05AJ04) cabotegravir

cabotegravir

(J05AX) Other antivirals

Other antivirals

Medical condition to be studied

Human immunodeficiency virus transmission

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

0

Study design details

Outcomes

• Clinical effectiveness

• Regimen discontinuation

• Adherence

• Resistance testing at virologic failure and next treatment response

Data analysis plan

Descriptive analyses will summarize the study population exposed to CAB+RPV LA. Proportions and multivariable regression models will be used to assess the factors associated with virologic failure, non-adherence, discontinuation of CAB+RPV LA regimen and resistance among participants with virologic failure.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No