Multi-country, non-interventional, cohort study of the effectiveness, safety, adherence, and health-related quality of life in HIV-1 infected adult patients receiving Bictegravir/ Emtricitabine/Tenofovir alafenamide (B/F/TAF) (BIC-STaR)

First published: 09/02/2018

Last updated: 26/07/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/40000

EU PAS number

EUPAS22185

Study ID

40000

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany
- [ ] Ireland
- [ ] Italy
- [ ] Netherlands
- [ ] Spain
- [ ] Türkiye
- [ ] United Kingdom

Study description

GS-EU-380-4472: This non-interventional cohort study will evaluate the effectiveness, safety, adherence, resource utilization and patients' health condition via Patient Reported Outcome (PRO) questionnaires, during treatment with B/F/TAF in routine clinical care.

Study status

Ongoing

Research institutions and networks

Institutions

Gilead Sciences

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Institution | Pharmaceutical company

Contact details

Study institution contact

Gilead Study Director

Study contact

ClinicalTrialDisclosure@gilead.com

Primary lead investigator

Gilead Study Director

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 08/09/2017

Actual: 11/09/2017

Study start date

Planned: 15/06/2018

Actual: 28/06/2018

Data analysis start date

Actual: 29/03/2019

Date of final study report

Planned: 18/04/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Gilead Sciences Europe Ltd

Study protocol

GS-EU-380-4472-appendix-16.1.1-protocol_f-redact.pdf(1.13 MB)

GS-EU-380-4472-appendix-16.1.1-protocol amendment 4_f-redact.pdf(2.46 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Main study objective:

The primary objective of this study is to evaluate the effectiveness, safety, adherence, and health-related quality of life in HIV-1 infected adult patients receiving bictegravir/ emtricitabine/tenofovir alafenamide (B/F/TAF).

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Prospective, non-interventional

Study drug and medical condition

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

BICTEGRAVIR

EMTRICITABINE

TENOFOVIR ALAFENAMIDE

Medical condition to be studied

HIV infection

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

1500

Study design details

Outcomes

To evaluate HIV-1 RNA suppression, defined as HIV-1 RNA < 50 copies/mL, at 12 months after initiating or switching to B/F/TAF. Evaluate HIV-1 RNA suppression (<50 copies/mL) at Months 3, 6, and 24, changes in cluster determinant 4 (CD4) cell count, CD4/CD8 ratio at Months 3, 6, 12, and 24 for all patients, assess rates of adverse events (AEs) and serious AEs, Evaluate long-term effectiveness at Month 36, 48, and 60 and safety for patients in Germany & France (in an extension phase).

Data analysis plan

For categorical variables, numbers and percentages of patients will be reported including the according 95% confidence intervals. For continuous variables, mean, standard deviation (SD), minimum, first and third quartile (Q1, Q3), median, maximum and 95% confidence intervals will be calculated, together with the total number of observations and the number of missing values. Descriptive statistics will summarize demographics and baseline characteristics (including the type of regimen at enrolment). Once data is available from more

than one country, descriptive analyses by country will be done to determine if patient heterogeneity exists across countries and sites. The questionnaires scores will be calculated according to the algorithms elaborated for these questionnaires.

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

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes