Post-marketing study to assess the effectiveness of doravirine-included in highly active antiretroviral therapy (HAART) in HIV-1 infected adult Chinese patients (MK-1439-088)

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Administrative details

EU PAS number

EUPAS103993

Study ID

106122

DARWIN EU® study

No

Study countries

China

Study description

Human immunodeficiency virus (HIV) is the etiologic agent of acquired immunodeficiency syndrome (AIDS).

The HIV infection (mainly HIV-1 infection) epidemic in China has evolved significantly over the past 35 years and it remains a major public health problem.

Doravirine (DOR, tradename PIFELTRO[™]) is a nonnucleoside reverse transcriptase inhibitors (NNRTI) that is indicated in combination with other antiretroviral medicinal products for the treatment of adults infected with HIV-1 without resistance to the NNRTI class.

Doravirine, lamivudine, tenofovir disoproxil fumarate(DOR/3TC/TDF, tradename DELSTRIGO^m) is a fixed-dose combination indicated for the treatment of adults infected with HIV-1. PIFELTRO^m and DELSTRIGO^m were approved in China in 2020.

The study aims to assess the effectiveness of doravirine-included highly active antiretroviral therapy (HAART) in HIV-1 infected adult Chinese participants by a retrospective observational study design using medical chart review.

Study status

Finalised

Research institutions and networks

Institutions

Merck & Co.

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Contact details

Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme LLC ClinicalTrialsDisclosure@merck.com

Study contact

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Primary lead investigator

Clinical Trials Disclosure Merck Sharp & Dohme LLC

Primary lead investigator

Study timelines

Date when funding contract was signed Actual: 18/08/2021

Study start date Planned: 31/07/2023 Actual: 25/07/2023

Data analysis start date Planned: 15/11/2024 Actual: 30/09/2024

Date of final study report

Planned: 28/02/2025 Actual: 13/02/2025

Sources of funding

• Pharmaceutical company and other private sector

More details on funding

Merck Sharp & amp, Dohme LLC

Study protocol

MK-1439-088-00-v1-Protocol_final redaction.pdf(1.02 MB)

MK-1439-088-00-v2-Protocol_final redaction (002).pdf(1 MB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)? Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

The primary objective is to assess the effectiveness of doravirine-included HAART in HIV-1 infected adult Chinese participants.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective multi-center observational study

Study drug and medical condition

Name of medicine

PIFELTRO

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

Anatomical Therapeutic Chemical (ATC) code

(J05AG06) doravirine doravirine

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)

Special population of interest

Hepatic impaired Immunocompromised Renal impaired

Estimated number of subjects

350

Study design details

Outcomes

Virologic suppression (VS, HIV-1 RNA< 50 copies/mL) achieved at week 48±8 following PIFELTROTM and DELSTRIGOTM administration.

Demographics, clinical characteristics and HIV-1 treatment patterns in the study population.

Data analysis plan

A descriptive analysis will be conducted. For the continuous variables we are interested, the values of mean/median, standard deviation (SD), min/max, interquartile range (IQR, including the first quartile Q1 and third quartile Q3) will be calculated, the frequency and percentages will be calculated for these categorical variables.

Effectiveness will be assessed as the proportion of patients with VS at week 48 ± 8 will be calculated with a 95% CI.

Documents

Study report

MK-1439 P088 CSR_final-redaction.pdf(584.29 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Retrospective data collection by chart review

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