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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Last updated: 07/05/2025





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 $^{\text{TM}}$) is a fixed-dose combination indicated for the treatment of adults infected with HIV-1. PIFELTRO $^{\text{TM}}$ and DELSTRIGO $^{\text{TM}}$ 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 Sharp & Dohme LLC
United States
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Pharmaceutical company

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 & 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

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

Other	
Data sources (types), other	
Retrospective data collection by chart review	
Use of a Common Data Model (CD	M)
CDM mapping	
No	
Data quality specifications	
Check conformance	
Unknown	
Check completeness	
Unknown	
Check stability	
Unknown	

Data characterisation

Data characterisation conducted

No