# 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)

**First published:** 23/03/2023

**Last updated:** 07/05/2025

Study Finalised

## 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™) is a fixed-dose combination indicated for the treatment of adults infected with HIV-1. PIFELTRO™ and DELSTRIGO™ 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.

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**Study status**

Finalised

# Research institutions and networks

## Institutions

### Merck Sharp & Dohme LLC

United States

**First published:** 01/02/2024

**Last updated:** 08/07/2025

Institution | Pharmaceutical company

## Contact details

### Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme LLC

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Study contact

ClinicalTrialsDisclosure@merck.com

### 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

**Medicinal product name**

PIFELTRO

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

DORAVIRINE

**Anatomical Therapeutic Chemical (ATC) code**

(J05AG06) doravirine

doravirine

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**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)

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**Special population of interest**

Hepatic impaired

Immunocompromised

Renal impaired

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**Estimated number of subjects**

350

# Study design details

**Outcomes**

Virologic suppression (VS, HIV-1 RNA< 50 copies/mL) achieved at week 48±8 following PIFELTRO™ and DELSTRIGO™ administration.
Demographics, clinical characteristics and HIV-1 treatment patterns in the study population.

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**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

**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