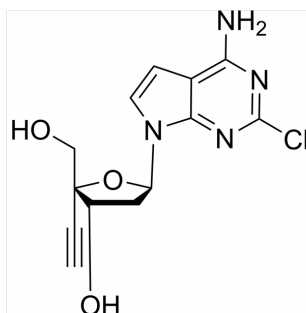


Developed by



Supported by



**MK-8527**

## Developer(s)

Merck

Originator

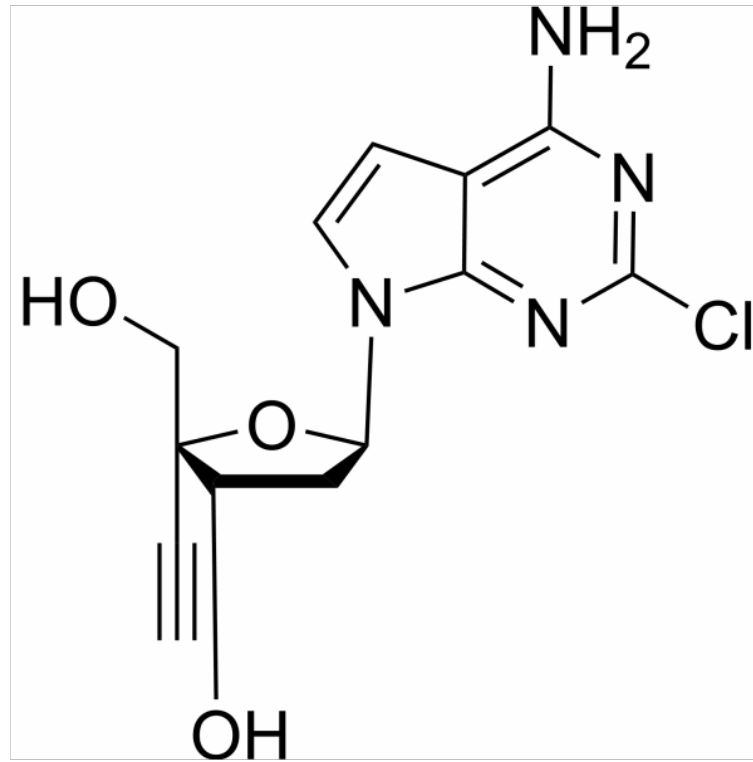
<https://www.merck.com/>

United States



Merck & Co., Inc. is an American multinational pharmaceutical company known as Merck Sharp & Dohme (MSD) in territories outside of the USA and Canada. Merck was originally established in 1891, and is currently headquartered in Rahway, New Jersey. The company is particularly well known for developing and manufacturing biologic therapies, vaccines, medicines and animal health products.

## Drug structure



MK-8527 Compound Structure Placeholder

# Drug information

## Associated long-acting platforms

Oral solid form

## Administration route

Oral

## Therapeutic area(s)

HIV

## Use case(s)

Pre-Exposure Prophylaxis (PrEP)

Treatment

## Use of drug

### Ease of administration

Self-administered

### User acceptance

Not provided

## Drug information

### Drug's link(s)

Not provided

### Generic name

MK-8527

### Brand name

Not provided

### Compound type

Small molecule

### Summary

MK-8527 is a novel nucleoside reverse transcriptase translocation inhibitor (NRTTI) currently in clinical development for the prevention and treatment of HIV-1. MK-8527 functions by preventing the translocation of the HIV reverse transcriptase enzyme, thereby disrupting viral replication. A Phase II study assessing MK-8257 as once-monthly oral PrEP in participants at low-risk for HIV-1 infection is currently in progress (NCT06045507).

### Approval status

Unknown

### Regulatory authorities

Unknown

### Delivery device(s)

No delivery device



# **Scale-up and manufacturing prospects**

## **Scale-up prospects**

Not provided

## **Tentative equipment list for manufacturing**

Not provided

## **Manufacturing**

Not provided

## **Specific analytical instrument required for characterization of formulation**

Not provided

# Clinical trials

**MK-8527-007**

## Identifier

NCT06045507

## Link

<https://clinicaltrials.gov/study/NCT06045507>

## Phase

Phase II

## Status

Recruiting

## Sponsor

Merck Sharp & Dohme LLC

## More details

Not provided

## Purpose

Evaluate the Safety, Tolerability, and Pharmacokinetics of Oral MK-8527 Once Monthly in Participants at Low-Risk for HIV-1 Infection.

## Interventions

### Intervention 1



Drug: MK-8527

## **Intervention 2**

Drug: Placebo to MK-8527

## **Countries**

United States of America

Israel

South Africa

## **Sites / Institutions**

Not provided

## **Trials dates**

### **Anticipated Start Date**

Not provided

### **Actual Start Date**

2023-11-08

### **Anticipated Date of Last Follow-up**

Not provided

### **Estimated Primary Completion Date**

2025-02-18

### **Estimated Completion Date**

2025-02-18

### **Actual Primary Completion Date**

Not provided

### **Actual Completion Date**

Not provided

## **Studied populations**

## **Age Cohort**

- Adults
- Older Adults

## **Genders**

- All

## **Accepts pregnant individuals**

No

## **Accepts lactating individuals**

No

## **Accepts healthy individuals**

Yes

## **Comments about the studied populations**

Participants aged 18 to 65 years who are confirmed HIV-uninfected with low-risk of acquiring HIV. Participants are excluded if they have prior use of either islatravir (MK-8591) or MK-8527.

## **Health status**

Considered at low risk of : HIV

Negative to : HIV, HCV, HBV

## **Study type**

Interventional (clinical trial)

## **Enrollment**

350

## **Allocation**

Randomized

### **Intervention model**

Parallel Assignment

### **Intervention model description**

Not provided

### **Masking**

Double-blind masking

### **Masking description**

Double (Participant, Investigator)

### **Frequency of administration**

Monthly

### **Studied LA-formulation(s)**

Other(s) : "Oral Capsule "

### **Studied route(s) of administration**

Oral

### **Use case**

PrEP

### **Key results**

Not provided

**MK-8527-002**

**Identifier**

NCT03615183

**Link**

<https://clinicaltrials.gov/study/NCT03615183>

**Phase**

Phase I

**Status**

Completed

**Sponsor**

Merck Sharp & Dohme LLC

**More details**

Not provided

**Purpose**

Evaluate the Safety, Tolerability, Pharmacokinetics, and Anti-Retroviral Activity of MK-8527 Monotherapy in Anti-Retroviral Therapy (ART)-Naïve, HIV-1 Infected Participants.

**Interventions**

**Intervention 1**

Drug: MK-8527

**Countries**

Romania

## **Sites / Institutions**

Not provided

## **Trials dates**

### **Anticipated Start Date**

Not provided

### **Actual Start Date**

2019-02-11

### **Anticipated Date of Last Follow-up**

Not provided

### **Estimated Primary Completion Date**

Not provided

### **Estimated Completion Date**

Not provided

### **Actual Primary Completion Date**

2019-09-26

### **Actual Completion Date**

2019-09-26

## **Studied populations**

### **Age Cohort**

- Adults

### **Genders**

- All

### **Accepts pregnant individuals**

No

**Accepts lactating individuals**

Unspecified

**Accepts healthy individuals**

No

**Comments about the studied populations**

Participants are ART-naïve HIV-1 positive individuals with a Body Mass Index (BMI)  $\leq 35$  kg/m<sup>2</sup>, inclusive.

**Health status**

Negative to : HCV, HBV

Positive to : HIV

**Study type**

Interventional (clinical trial)

**Enrollment**

17

**Allocation**

Randomized

**Intervention model**

Sequential assignment

**Intervention model description**

Not provided

**Masking**

Open label

**Masking description**

None (Open Label)

**Frequency of administration**

Other(s) : "Single dose "

**Studied LA-formulation(s)**

Other(s) : "Oral Capsule "

**Studied route(s) of administration**

Oral

**Use case**

Treatment

**Key results**

Not provided

**MK-8527-004**

**Identifier**

NCT05494736

**Link**

<https://clinicaltrials.gov/study/NCT05494736>

**Phase**

Phase I

**Status**

Completed

**Sponsor**

Merck Sharp & Dohme LLC

**More details**

Not provided

**Purpose**

Evaluate the Safety, Tolerability, Pharmacokinetics, and Anti-Retroviral Activity of a Single Dose of MK-8527 Monotherapy in Anti-Retroviral Therapy (ART)-Naïve, HIV-1 Infected Participants.

**Interventions**

**Intervention 1**

Drug: MK-8527

**Countries**



Romania

South Africa

## **Sites / Institutions**

Not provided

## **Trials dates**

### **Anticipated Start Date**

Not provided

### **Actual Start Date**

2022-11-17

### **Anticipated Date of Last Follow-up**

Not provided

### **Estimated Primary Completion Date**

Not provided

### **Estimated Completion Date**

Not provided

### **Actual Primary Completion Date**

2024-01-31

### **Actual Completion Date**

2024-01-31

## **Studied populations**

### **Age Cohort**

- Adults

### **Genders**

- All

**Accepts pregnant individuals**

No

**Accepts lactating individuals**

No

**Accepts healthy individuals**

No

**Comments about the studied populations**

Participants are ART-naïve HIV-1 positive individuals aged 18-60 years.

**Health status**

Negative to : HBV

Positive to : HIV

**Study type**

Interventional (clinical trial)

**Enrollment**

20

**Allocation**

Non-randomized

**Intervention model**

Sequential assignment

**Intervention model description**

Not provided

**Masking**

Open label

**Masking description**

None (Open Label)

**Frequency of administration**

Other(s) : "Single dose "

**Studied LA-formulation(s)**

Other(s) : "Oral Capsule "

**Studied route(s) of administration**

Oral

**Use case**

Treatment

**Key results**

Not provided

# MK-8527-008

## Identifier

NCT06295796

## Link

<https://clinicaltrials.gov/study/NCT06295796>

## Phase

Phase I

## Status

Not yet recruiting

## Sponsor

Merck Sharp & Dohme LLC

## More details

The goal of this study is to evaluate the effect of moderate and severe renal impairment (RI) on the pharmacokinetics (PK), safety, and tolerability of MK-8527. There will be no hypothesis testing in the study.

## Purpose

A Study of MK-8527 in Participants With Moderate and Severe Renal Impairment (MK-8527-008)

## Interventions

### Intervention 1

MK-8527

## **Countries**

Not provided

## **Sites / Institutions**

Not provided

## **Trials dates**

### **Anticipated Start Date**

Not provided

### **Actual Start Date**

2024-06-24

### **Anticipated Date of Last Follow-up**

2024-04-30

### **Estimated Primary Completion Date**

2024-03-06

### **Estimated Completion Date**

2024-03-06

### **Actual Primary Completion Date**

2024-05-01

### **Actual Completion Date**

2025-04-21

## **Studied populations**

### **Age Cohort**

- Adults
- Older Adults

### **Genders**

All

**Accepts pregnant individuals**

Unspecified

**Accepts lactating individuals**

Unspecified

**Accepts healthy individuals**

Yes

**Comments about the studied populations**

Inclusion Criteria: The main inclusion criteria include but are not limited to the following: Moderate and Severe RI \* With the exception of RI, is in sufficient health for study participation. \* Has stable renal function. Healthy \* Matches mean age to participants with moderate and severe RI. \* Has normal renal function. Exclusion Criteria: The main exclusion criteria include but are not limited to the following: All participants \* History of cancer (malignancy). \* Positive test results for Human-immunodeficiency virus (HIV), Hepatitis B surface antigen (HBsAg), or Hepatitis C virus (HCV). \* Had a major surgery or lost significant volume of blood within 56 days prior to dosing. \* Donated plasma within 7 days prior to dosing. Moderate and Severe RI \* Failed renal transplant or h

**Health status**

Not provided

**Study type**

Interventional (clinical trial)

**Enrollment**

18

**Allocation**

Non-randomized

## **Intervention model**

Parallel Assignment

## **Intervention model description**

Not provided

## **Masking**

Open label

## **Masking description**

Not provided

## **Frequency of administration**

Not provided

## **Studied LA-formulation(s)**

Not provided

## **Studied route(s) of administration**

Oral

## **Use case**

Treatment

## **Key results**

Not provided

# Excipients

## **Proprietary excipients used**

Not provided

## **Novel excipients or existing excipients at a concentration above Inactive Ingredients Database (IID) for the specified route of administration**

Not provided

## **Residual solvents used**

Not provided



## Patent info

## Description

4'-SUBSTITUTED NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITORS

## Brief description

4'-substituted nucleoside derivatives of Formula I and their use in the inhibition of HIV reverse transcriptase, the prophylaxis of infection by HIV, the treatment of infection by HIV, and the prophylaxis, treatment, and delay in the onset or progression of AIDS and/or ARC.

## Representative patent

WO2015143712

## Category

Compound

## Patent holder

Merck Sharp & Dohme Corp.

## Exclusivity

Not provided

## Expiration date

March 28, 2034

## Status

Granted in 36 countries: AL, AM, AP (BW, GH, KE, NA), AT, AU, AZ, BA, BE, BG, BY, CA, CH, CL, CN, CR, CY, CZ, DE, DK, DZ, EA, EE, ES, FI, FR, GB, GC, GE, GI, GR, GY, HN, HR, HU, ID, IE, IL, IR, IS, IT, JO, JP, KR, KZ, LB, LT, LU, LV, MA, ME, MK, MN, MT, MX, MY, NG, NL, NO, NZ, PA, PE, PH, PK, PL, PT, RO, RS, RU, SC, SE, SG, SI, SK, TN, TR, TT, TW, UA, US, VE, VN, ZA Filed in 13 countries: AR, BB, BN, BR, BZ, DO, EC, EG, GT, IN, JM, LK, NI, SV, TH As of 27 June 2024 - MPP Search



# Supporting material

## Publications

There are no publication

## Additional documents

No documents were uploaded

## Useful links

There are no additional links

# Access principles

## Collaborate for development



Consider on a case by case basis, collaborating on developing long acting products with potential significant public health impact, especially for low- and middle-income countries (LMICs), utilising the referred to long-acting technology

Not provided

## Share technical information for match-making assessment



Provide necessary technical information to a potential partner, under confidentiality agreement, to enable preliminary assessment of whether specific medicines of public health importance in LMICs might be compatible with the referred to long-acting technology to achieve a public health benefit

Not provided

## Work with MPP to expand access in LMICs



In the event that a product using the referred to long-acting technology is successfully developed, the technology IP holder(s) will work with the Medicines Patent Pool towards putting in place the most appropriate strategy for timely and affordable access in low and middle-income countries, including through licensing

Not provided

## Comment & Information

Not provided