LAPaL
THE LONG-ACTING THERAPEUTICS PATENTS AND LICENCES DATABASE

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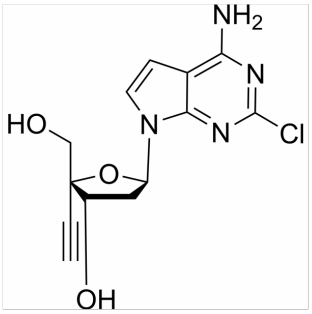


MK-8527

Developer(s)

Merck

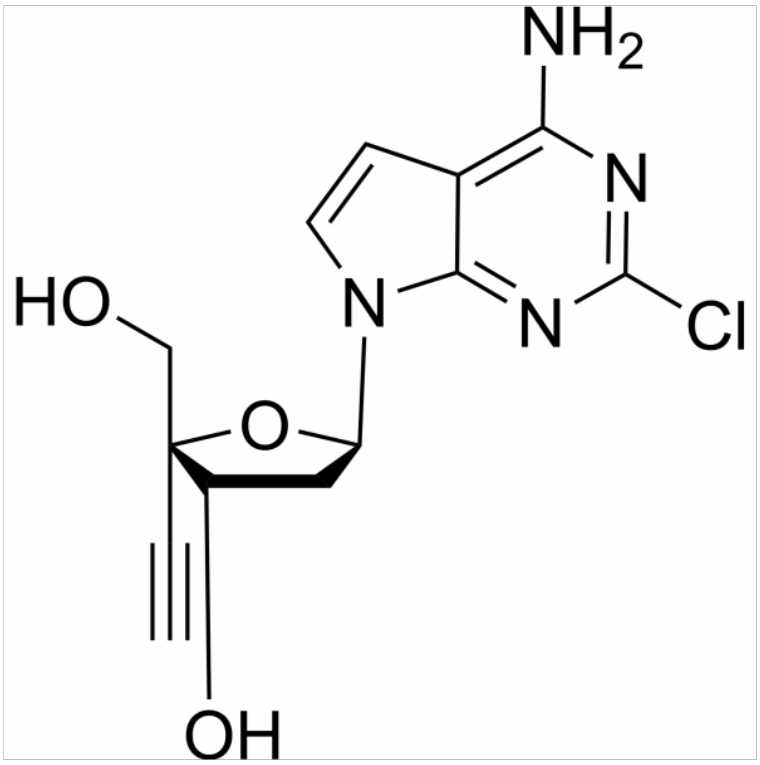
Originator

https://www.merck.com/

United States

Merck & Co., Inc. is an American multinational pharmaceutical company known as Merck Sharp & Drone (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) ≤35 kg/m^2, 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