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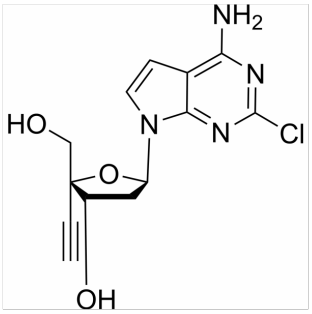


MK-8527

Developer(s)

Merck

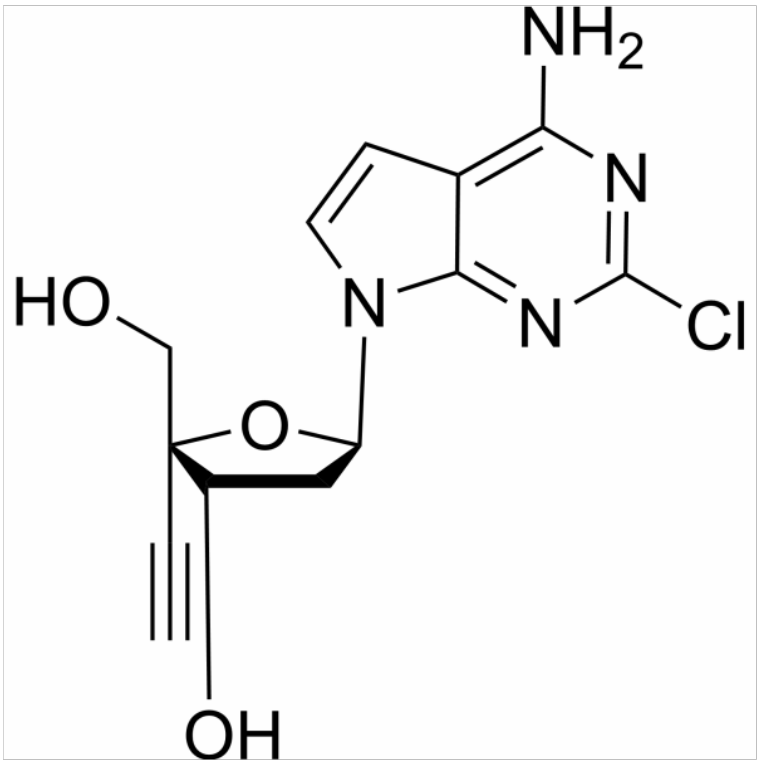
Originator

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 (4'-ethynyl-2-fluoro-2'-deoxyadenosine)

Drug information

Associated long-acting platforms

Oral solid form

Administration route

Oral

Therapeutic area(s)

HIV

Use case(s)

Pre-Exposure Prophylaxis (PrEP)
Prevention

Use of drug

Ease of administration

Self-administered

User acceptance

A monthly oral PrEP option would probably fit well in many settings and be convenient for a number of clients. This will be further investigated. In safety and tolerability trials, in healthy male and female adult populations, MK-8527 was well tolerated. In Phase 1 studies, AEs were reported by the majority of participants (79 -90%), with top AEs being headache, influenza-like illness, cough, abdominal pain, nausea. No serious AEs or events of clinical interest were reported. There seemed to be no difference in meal fat content on the drug levels.

Dosage

Available dose and strength

Doses of 0.25 mg, 0.5mg, 1mg, 3mg, 10 mg and 12 mg are being evaluated in clinical programs.

Frequency of administration

Investigated for once monthly oral dosing for HIV PrEP

Maximum dose

Doses of 0.25 mg, 0.5mg, 1mg, 3mg and 10 mg are being evaluated in clinical programs.

Recommended dosing regimen

Doses of 0.25 mg, 0.5mg, 1mg, 3mg and 10 mg are being evaluated in clinical programs as once monthly oral dosing

Additional comments

MK-8527 is on the priority list of MPP since March 2025, as a candidate for which voluntary licensing and technology transfer through MPP would lead to expanded access, significant health benefits, and substantial public health impact compared to available standards of care (https://medicinespatentpool.org/progress-achievements/prioritisation#pills-hiv)

Dosage link(s)

Not provided

Drug information

Drug's link(s)

Not provided

Generic name

MK-8527

Brand name

investigational

Compound type

Small molecule

Summary

MK-8527 is a nucleoside reverse transcriptase translocation inhibitor (NRTTI) currently in clinical development for the prevention of HIV-1 by oral route. Ongoing trials are assessing MK-8257 as a once-monthly oral PrEP option. MK-8257 is a similar compound to islatravir. MK-8527 is a 7-deaza-deoxyadenosine analog and is phosphorylated intracellularly to its active triphosphate (TP) form, which is a potent inhibitor of HIV-1 replication. MK-8527 functions by preventing the translocation of the HIV reverse transcriptase enzyme, thereby disrupting viral replication. Pre-clinical studies suggest that MK-8527 has a sub-nanomolar potency and no off-target activity. Apparent terminal half-life of MK-8527 triphosphate was 216-291 hrs. Observed reduced viral load by at least –1.0 log after 7 days.

Approval status

MK-8527 is currently in clinical development and not yet approved in any jurisdiction.

Regulatory authorities

MK-8527 is currently in clinical development and not yet approved in any jurisdiction.

Delivery device(s)

No delivery device

Scale-up and manufacturing prospects

Scale-up prospects

Detailed manufacturing information is not currently available for this compound.

Tentative equipment list for manufacturing

Detailed manufacturing information is not currently available for this compound.

Manufacturing

Detailed manufacturing information is not currently available for this compound.

Specific analytical instrument required for characterization of formulation

Detailed manufacturing information is not currently available for this compound.

Clinical trials

MK-8527-007 - QM PrEP

Identifier

NCT06045507

Link

https://clinicaltrials.gov/study/NCT06045507

Phase

Phase II

Status

Completed

Sponsor

Merck Sharp & Dohme LLC

More details

This double-blind, placebo-controlled study is designed to assess the safety, tolerability, and pharmacokinetics of oral MK-8527 taken once monthly (QM) in participants at low risk for human immunodeficiency virus Type 1 (HIV-1) infection.

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

MK-8527 Low Dose QM for 6 months

Dosage: 3mg oral capsule

Intervention 2

Medium Dose QM for 6 months

Dosage: 6mg oral capsule

Intervention 3

MK-8527 High Dose QM for 6 months

Dosage: 12mg oral capsule

Intervention 4

Placebo to MK-8527 for 6 months

Dosage: oral capsule

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

2025-03-11

Estimated Primary Completion Date

2025-02-18

Estimated Completion Date

2025-02-18

Actual Primary Completion Date

2024-12-12

Actual Completion Date

2025-02-12

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
Other health status: excluded if previous use of islatravir or MK-8527

Study type

Interventional (clinical trial)

Enrollment

352

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Participants receive the intervention for 6 months and are then followed-up for 8 weeks blinded safety period.

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 resources

Type	Title	Content	Link
Link	South African National Clinical Trials Registry		https://sanctr.samrc.ac.za/T
Link	MK-8527 PK/PD Threshold and Phase II Dose Selection for Monthly Oral HIV-1 Preexposure Prophylaxis - CROI2025- abstract 1232		https://www.croiconference.2025/

MK-8527-002 - monotherapy antiviral

Identifier

NCT03615183

Link

https://clinicaltrials.gov/study/NCT03615183

Phase

Phase I

Status

Completed

Sponsor

Merck Sharp & Dohme LLC

More details

This study will evaluate the anti-retroviral activity of MK-8527 in HIV-1 infected, ART-naïve participants. The primary hypothesis is that MK-8527 has superior anti-retroviral activity compared to placebo, as measured by change from baseline in plasma HIV-1 ribonucleic acid (RNA) at 168 hours postdose.

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

A-MK-8527

Dosage: Single oral dose of 10 mg MK-8527 capsule after an 8-hour fast

Intervention 2

B-MK-8527

Dosage: Single oral dose of 3 mg MK-8527 capsule after an 8-hour fast

Intervention 3

C-MK-8527

Dosage: Single oral dose of 1 mg MK-8527 capsule after an 8-hour fast

Intervention 4

MK-8527

Dosage: Single oral dose of ≤50 mg MK-8527 capsule after an 8-hour fast

Intervention 5

MK-8527

Dosage: Another single oral dose of ≤50 mg MK-8527 capsule after an 8-hour fast.

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

2020-09-04

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

Other health status: Diagnosed with HIV-1 infection ≥ 3 months prior to screening

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

Once

Studied LA-formulation(s)

Other(s) : "Oral Capsule "

Studied route(s) of administration

Oral

Use case

PrEP

Key resources

Type	Title	Content	Link
Link	Single Dose Administration of MK-8527, a Novel nRTTI, in Adults With HIV-1		https://www.croiconference.dose-administration-of-mk-8527-a-novel-nrtti-in-adults-with-hiv-1/
Link	Clinical trial results of MK-8527-002 on clinicaltrials.gov		https://clinicaltrials.gov/stud 8527&rank=6&tab=results

MK-8527-004 - monotherapy antiviral

Identifier

NCT05494736

Link

https://clinicaltrials.gov/study/NCT05494736

Phase

Phase I

Status

Completed

Sponsor

Merck Sharp & Dohme LLC

More details

Activity of MK-8527 Monotherapy in Anti-Retroviral Therapy (ART)-Naïve, HIV-1 Infected Participants

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

A-MK-8527

Dosage: single oral dose of MK-8527 1.0 mg

Intervention 2

C-MK-8527

Dosage: single oral dose of MK-8527 0.25 mg

Intervention 3

B-MK-8527

Dosage: single oral dose of MK-8527 0.5 mg

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

2025-03-06

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, HCV
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 : "Single dose "
Once
Monthly

Studied LA-formulation(s)

Other(s) : "Oral Capsule "

Studied route(s) of administration

Oral

Use case

PrEP

Key resources

Type	Title	Content	Link

Link	Single Dose Administration of MK-8527, a Novel nRTTI, in Adults With HIV-1	https://www.croiconference.dose-administration-of-mk-8527-a-novel-nrtti-in-adults-with-hiv-1/
Link	AVAC trial entry	https://avac.org/trial/mk-8527-004/
Link	Study Protocol	https://cdn.clinicaltrials.gov/docs/36/NCT05494736/Prot_
Link	Safety and Pharmacokinetics of MK-8527, a Novel nRTTI, in Adults Without HIV	https://www.croiconference.and-pharmacokinetics-of-mk-8527-a-novel-nrtti-in-adults-without-hiv/
Link	Key results on Clinicaltrials.gov	https://clinicaltrials.gov/stud 8527&rank=1&tab=results

MK-8527-008 - renal impairment

Identifier

NCT06295796

Link

https://clinicaltrials.gov/study/NCT06295796

Phase

Phase I

Status

Completed

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

United States of America

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2024-06-20

Anticipated Date of Last Follow-up

2025-02-05

Estimated Primary Completion Date

2024-03-06

Estimated Completion Date

2024-03-06

Actual Primary Completion Date

2025-01-31

Actual Completion Date

2025-01-31

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
Other health status: Participants With Moderate and Severe Renal Impairment

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

Once

Studied LA-formulation(s)

Other(s) : "Oral Capsule "

Studied route(s) of administration

Oral

Use case

PrEP

Key resources

Not provided

MK-8527-012 - CBZ

Identifier

NCT06893081

Link

https://clinicaltrials.gov/study/NCT06893081

Phase

Phase I

Status

Active, not recruiting

Sponsor

Merck Sharp & Dohme LLC

More details

The goal of this study is to learn what happens to MK-8527 in a healthy person's body over time when MK-8527 is given alone and with the medication CBZ. Carbamazepine, sold under the brand name Tegretol among others, is an anticonvulsant medication used in the treatment of epilepsy and neuropathic pain. It is used as an adjunctive treatment in schizophrenia along with other medications and as a second-line agent in bipolar disorder.

Purpose

A Study of Carbamazepine (CBZ) and MK-8527 in Healthy Adult Participants (MK-8527-012)

Interventions

Intervention 1

MK-8527

Intervention 2

CBZ

Countries

United States of America

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

2025-04-28

Actual Start Date

2025-04-28

Anticipated Date of Last Follow-up

2025-07-03

Estimated Primary Completion Date

2025-06-19

Estimated Completion Date

2025-07-11

Actual Primary Completion Date

2025-06-19

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adults

Genders

- All

Accepts pregnant individuals

No

Accepts lactating individuals

No

Accepts healthy individuals

Yes

Comments about the studied populations

Inclusion Criteria: Inclusion criteria include, but are not limited to: * Is a healthy, adult, male or female of non-childbearing potential only, 18-55 years of age, inclusive * Is a continuous non-smoker who has not used nicotine- and tobacco-containing products for at least 3 months prior Exclusion Criteria: Exclusion criteria include, but are not limited to: * Has a history or presence of: * Seizures (except for febrile seizure), or is at an increased risk for seizures * Family history of severe dermatologic reactions including toxic epidermal necrolysis and Stevens-Johnson syndrome * Clinically meaningful hematologic diseases, bone marrow disorders, or hematologic adverse reactions to other medications * Depression, unusual changes in mood or behavior or suicidal thoughts

Health status

Negative to : HIV

Study type

Interventional (clinical trial)

Enrollment

16

Allocation

Non-randomized

Intervention model

Single group assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Monthly

Studied LA-formulation(s)

Other(s) : "Oral Capsule "

Studied route(s) of administration

Oral

Use case

PrEP

Key resources

Not provided

MK-8527-005 - multiple dose PK

Identifier

EUCT2022-502081-24-00

Link

https://euclinicaltrials.eu/search-for-clinical-trials/?lang=en&EUCT=2022-502081-24-00

Phase

Phase I

Status

Completed

Sponsor

Merck Sharp & Dohme LLC

More details

A Multiple-Dose Clinical Study to Evaluate Safety, Tolerability, and Pharmacokinetics of MK-8527 in Healthy Participants

Purpose

A Multiple-Dose Clinical Study to Evaluate Safety, Tolerability, and Pharmacokinetics of MK-8527 in Healthy Participants

Interventions

Intervention 1

MK-8527

Countries

Belgium

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

2022-12-07

Actual Start Date

Not provided

Anticipated Date of Last Follow-up

Not provided

Estimated Primary Completion Date

Not provided

Estimated Completion Date

2023-06-14

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adults
- Older Adults

Genders

- Male

Female

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

Yes

Comments about the studied populations

18-64 years

Health status

Negative to : HIV

Study type

Interventional (clinical trial)

Enrollment

Not provided

Allocation

Non-randomized

Intervention model

Single group assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Once

Studied LA-formulation(s)

Other(s) : "Oral Capsule "

Studied route(s) of administration

Oral

Use case

PrEP

Key resources

Type	Title	Content	Link
Link	Safety and Pharmacokinetics of MK-8527, a Novel nRTTI, in Adults Without HIV		https://www.croiwebcasts.or

MK-8527-013 - PK/PD

Identifier

NCT06826989

Link

https://clinicaltrials.gov/study/NCT06826989

Phase

Phase I

Status

Recruiting

Sponsor

Merck Sharp & Dohme LLC

More details

The goal of this study is to learn how MK-8527 moves through a healthy person's body over time. Researchers will study how MK-8527 is absorbed by the body, broken down by the body, and how it leaves the body.

Purpose

A Study of MK-8527 in Healthy Adult Participants (PK PD) (MK-8527-013)

Interventions

Intervention 1

MK-8527

Dosage: single oral dose

Countries

United States of America

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2025-03-19

Anticipated Date of Last Follow-up

2025-04-07

Estimated Primary Completion Date

2025-05-07

Estimated Completion Date

2025-05-21

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adults

Genders

- Male

Accepts pregnant individuals

No

Accepts lactating individuals

No

Accepts healthy individuals

Yes

Comments about the studied populations

Inclusion Criteria: * Is in good health * Has a body mass index (BMI) of 18 to 32 kg/m\^2 Exclusion Criteria: * Has a history of cancer * Has positive tests for hepatitis B surface antigen, hepatitis C antibodies or human immunodeficiency virus

Health status

Negative to : HBV, HCV, HIV
Other health status: body mass index (BMI) of 18 to 32 kg/m^2

Study type

Interventional (clinical trial)

Enrollment

8

Allocation

Non-randomized

Intervention model

Single group assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Once
Monthly

Studied LA-formulation(s)

Other(s) : "Oral Capsule "

Studied route(s) of administration

Oral

Use case

PrEP

Key resources

Not provided

MK-8527-009 - Breast Milk

Identifier

NCT06580587

Link

https://clinicaltrials.gov/study/NCT06580587

Phase

Phase I

Status

Recruiting

Sponsor

Merck Sharp & Dohme LLC

More details

The goal of this study is to learn how MK-8527 moves through the healthy person's body over time. Researchers will measure for the amount of MK-8527 in breast milk that the baby will receive at many time points.

Purpose

A Study of MK-8527 in Healthy Lactating Female Participants (MK-8527-009)

Interventions

Intervention 1

MK-8527 oral single dose

Countries

United States of America

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2025-04-15

Anticipated Date of Last Follow-up

2025-04-21

Estimated Primary Completion Date

2025-12-19

Estimated Completion Date

2025-12-19

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adults
- Older Adults

Genders

- Female

Accepts pregnant individuals

No

Accepts lactating individuals

Yes

Accepts healthy individuals

Yes

Comments about the studied populations

Inclusion Criteria: The key inclusion criteria include but are not limited to the following: * Is at least 6 weeks postpartum at the time of administration of study intervention, following the delivery of a healthy singleton neonate * Is willing and able to express breast milk at least twice daily for at least 120 hours after enrollment * Is willing to discontinue breastfeeding from the time of administration of study intervention until at least 6 weeks following the administration of study intervention. This includes the avoidance of both directly breastfeeding and the administration of breast milk pumped during the above-specified time frame to the infant. Is willing to confirm with the site that the infant is able to bottle feed (breast milk) prior to Day 1 and that alternative nutrit

Health status

Negative to : HBV, HCV, HIV
Other health status: Healthy Lactating Female Participants

Study type

Interventional (clinical trial)

Enrollment

12

Allocation

Non-randomized

Intervention model

Single group assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Once

Studied LA-formulation(s)

Other(s) : "Oral Capsule "

Studied route(s) of administration

Oral

Use case

PrEP

Key resources

Not provided

MK-8527-006 - LNG/EE

Identifier

NCT06783192

Link

https://clinicaltrials.gov/study/NCT06783192

Phase

Phase I

Status

Completed

Sponsor

Merck Sharp & Dohme LLC

More details

This study is designed to assess the effect of a single dose of MK-8527 on the single-dose pharmacokinetics (PK) and the safety and tolerability of levonorgestrel/ethinyl estradiol (LNG/EE) in healthy adult postmenopausal or ovariectomized female participants.

Purpose

A Drug-Drug Interaction Study of MK 8527 With a Combined Oral Contraceptive (LNG/EE) in healthy adult postmenopausal or ovariectomized female participants.

Interventions

Intervention 1

MK-8527

Intervention 2

LNG/EE levonorgestrel/ethinyl estradiol combination tablet taken by mouth

Countries

United States of America

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2023-08-14

Anticipated Date of Last Follow-up

2025-01-14

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2023-10-11

Actual Completion Date

2023-10-11

Studied populations

Age Cohort

Adults

- Older Adults

Genders

- Female

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

Yes

Comments about the studied populations

Inclusion Criteria: 18 Years to 70 Years (Adult, Older Adult) * is in good overall health * assigned female at birth Exclusion Criteria: * has a history of clinically significant endocrine, GI, cardiovascular, hematological, thromboembolic, hepatic, immunological, renal, respiratory, genitourinary, or major neurological (including stroke and chronic seizures) abnormalities or diseases * is mentally or legally incapacitated, has significant emotional problems at the time of prestudy (screening) visit or expected during the conduct of the study or has a history of clinically significant psychiatric disorder of the last 5 years * has a history of cancer (malignancy)

Health status

Negative to : HIV, HCV, HBV

Study type

Interventional (clinical trial)

Enrollment

14

Allocation

Non-randomized

Intervention model

Single group assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Monthly

Studied LA-formulation(s)

Other(s) : "Oral Capsule "

Studied route(s) of administration

Oral

Use case

PrEP

Key resources

Type	Title	Content	Link

Link	Phase 1, open-label study to evaluate the drug interaction between MK-8527, an HIV-1 nucleoside reverse transcriptase translocation inhibitor, and the oral contraceptive levonorgestrel/ethinyl estradi	https://www.natap.org/2024

MK-8527-016 - TDF/FTC

Identifier

NCT06816043

Link

https://clinicaltrials.gov/study/NCT06816043

Phase

Phase I

Status

Completed

Sponsor

Merck Sharp & Dohme LLC

More details

The goal of this study is to learn what happens to MK-8527 in a healthy person's body over time, called a pharmacokinetic (PK) study. Researchers want to learn if there is a difference in the healthy person's body when MK-8527 is taken as a single dose (Treatment A) or with the medication Emtricitabine/Tenofovir Disoproxil Fumarate (FTC/TDF) (Treatment B).

Purpose

A Study of Emtricitabine/Tenofovir Disoproxil Fumarate (FTC/TDF) and MK-8527 in Healthy Participants

Interventions

Intervention 1

MK-8527

Dosage: oral capsule

Intervention 2

FTC/TDF + MK-8527

Dosage: oral tablet + oral capsule

Countries

United States of America

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2025-02-21

Anticipated Date of Last Follow-up

2025-06-25

Estimated Primary Completion Date

2025-06-05

Estimated Completion Date

2025-06-05

Actual Primary Completion Date

2025-06-05

Actual Completion Date

2025-06-17

Studied populations

Age Cohort

- 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: * Continuous non-smoker who has not used nicotine- and tobacco-containing products for at least 3 months prior * Has body mass index (BMI) ≥18 and ≤32.0 kg/m\^2 Exclusion Criteria: The main exclusion criteria include but are not limited to the following: * History of low bone density, renal impairment, Fanconi syndrome, autoimmune disorders (such as Graves' disease, polymyositis, Guillain-Barré syndrome, and autoimmune hepatitis), liver disease * History of cancer (malignancy) * Positive results for human immunodeficiency virus (HIV), hepatitis B surface antigen (HBsAg), or hepatitis C virus (HCV)

Health status

Negative to : HIV, HCV, HBV
Other health status: 19 Years to 55 Years (Adult) Continuous non-smoker who has not used nicotine- and tobacco-containing products for at least 3 months prior Has body mass index (BMI) ≥18 and ≤32.0 kg/m^2

Study type

Interventional (clinical trial)

Enrollment

20

Allocation

Randomized

Intervention model

Cross-over assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Once
Monthly

Studied LA-formulation(s)

Other(s) : "Oral Capsule "

Studied route(s) of administration

Oral

Use case

PrEP

Key resources

Not provided

MK-8527-011 -EXPrESSIVE-11

Identifier

NCT07044297

Link

https://clinicaltrials.gov/study/NCT07044297

Phase

Phase III

Status

Not yet recruiting

Sponsor

Merck Sharp & Dohme LLC

More details

Researchers are looking for new medicines to prevent HIV-1 (Human Immunodeficiency Virus Type 1) infection. The goals of this study are to learn: * If taking MK-8527 once a month works to prevent HIV-1 infection as well as or better than a standard (usual) pre-exposure prophylaxis (PrEP) taken once a day * About the safety of MK-8527 and if people tolerate it

Purpose

A Clinical Study of MK-8527 to Prevent Human Immunodeficiency Virus Type 1 (HIV-1) (MK-8527-011)

Interventions

Intervention 1

MK-8527 oral tablet

Dosage: 11 mg MK-8527 once monthly (QM)

Intervention 2

Placebo to MK-8527

Intervention 3

FTC/TDF

Dosage: 200 mg FTC/245 mg TDF QD

Intervention 4

Placebo to FTC/TDF

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

2025-07-31

Actual Start Date

Not provided

Anticipated Date of Last Follow-up

2025-07-14

Estimated Primary Completion Date

2027-10-20

Estimated Completion Date

2027-10-20

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Children
- 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: * Is confirmed HIV-uninfected based on negative HIV-1/HIV-2 test results * Is a cisgender man, transgender woman (assigned male sex at birth), transgender man (assigned female sex at birth), or gender nonbinary person * Has had condomless receptive anal sex in the 12 months prior to screening (not including sex occurring in a mutually monogamous relationship) and has at least 1 of the following: receptive anal sex with 2 or more partners in the 3 months prior to screening (regardless of condom use), rectal or urethral gonorrhea or chlamydia or incident syphilis in the 6 months prior to screening, or any self-reported stimulant drug use with sex in the 3 months

prior to screening * Weighs ≥35 kg

Health status

Negative to : HIV, HBV
Other health status: 16 Years and older

Study type

Interventional (clinical trial)

Enrollment

4390

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Double-blind masking

Masking description

Not provided

Frequency of administration

Monthly

Studied LA-formulation(s)

Tablet

Studied route(s) of administration

Oral

Use case

PrEP

Key resources

Type	Title	Content	Link
Link	In collaboration with the Gates Foundation, Merck advances MK-8527 pre-exposure prophylaxis (PrEP) clinical trials globally		https://www.merck.com/new to-initiate-phase-3-trials-for-investigational-once-monthly-hiv-prevention-pill/

MK-8527-015 -Hepatic Impairment

Identifier

NCT07025551

Link

https://clinicaltrials.gov/study/NCT07025551

Phase

Phase I

Status

Not yet recruiting

Sponsor

Merck Sharp & Dohme LLC

More details

The purpose of this study is to learn what happens to MK-8527 in a person's body over time (a pharmacokinetic \[PK\] study). Researchers will compare what happens to MK-8527 in the body when it is given to healthy participants and participants with mild and moderate hepatic (liver) impairment.

Purpose

A Clinical Study of MK-8527 in Participants With Mild and Moderate Hepatic Impairment (MK-8527-015)

Interventions

Not provided

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

2025-08-11

Actual Start Date

Not provided

Anticipated Date of Last Follow-up

2025-06-09

Estimated Primary Completion Date

2026-02-05

Estimated Completion Date

2026-02-25

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

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: All participants: * Is a continuous non-smoker or moderate smoker (≤ 10 cigarettes per day or equivalent) for at least 3 months prior to dosing * Has body mass index (BMI) ≥ 18.0 and ≤ 40.0 kg/m\^2 * Has a diagnosis of chronic, stable, hepatic insufficiency with features of cirrhosis due to any etiology Participants with Mild HI (Group 1) and Moderate HI (Group 2): * Has mild or moderate hepatic impairment * Is generally in good health with the exception of HI Healthy Control Participants (Group 3): - Healthy with no clinically significant medical history, physical examination, clinical laboratory profiles, vital signs, and ECGs Exclusion Criteria: The main exclusion criteria include but

Health status

Negative to : HIV, HBV, HCV, oncology
Other health status: Researchers will compare what happens to MK-8527 in the body when it is given to participants with mild and moderate hepatic (liver) impairment.

Study type

Interventional (clinical trial)

Enrollment

18

Allocation

Not provided

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Monthly

Studied LA-formulation(s)

Tablet

Studied route(s) of administration

Oral

Use case

PrEP

Key resources

Not provided

MK-8527-014 -Moxifloxacin -QT

Identifier

NCT07063238

Link

https://clinicaltrials.gov/study/NCT07063238

Phase

Phase I

Status

Not yet recruiting

Sponsor

Merck Sharp & Dohme LLC

More details

Researchers are looking for new medicines to prevent Human Immunodeficiency Virus Type 1 (HIV-1) infection. HIV-1 is the most common type of HIV, which is a virus that attacks cells of the immune system. Medicines to prevent HIV-1 infection are called pre-exposure prophylaxis (PrEP). Some people may have trouble following a PrEP plan because it involves either taking medicine everyday by mouth or getting injections (shots) often. MK-8527 is a study medicine designed to prevent HIV-1 infection. MK-8527 is different from standard (usual) PrEP because it is taken once a month, by mouth, as a tablet. The goal of this study is to learn if taking a higher-than-normal dose of MK-8527 increases the QT interval (a measure of heart rhythm) by a certain amount.

Purpose

A Clinical Study of MK-8527 in Healthy Adult Participants (MK-8527-014)

Interventions

Intervention 1

MK-8527+Moxifloxacin+Placebo

Dosage: sequential

Intervention 2

Moxifloxacin+MK-8527+Placebo

Dosage: sequential

Intervention 3

Placebo+MK-8527+Moxifloxacin

Dosage: sequential

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

2025-07-22

Actual Start Date

Not provided

Anticipated Date of Last Follow-up

2025-07-03

Estimated Primary Completion Date

2025-09-09

Estimated Completion Date

2025-09-09

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- 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: * Is in good health before randomization * Has body mass index (BMI) between 18 and 32 kg/m\^2, inclusive Exclusion Criteria: The main exclusion criteria include but are not limited to the following: * Has history of clinically significant endocrine, gastrointestinal (GI), cardiovascular, hematological, hepatic, immunological, renal, respiratory, genitourinary, or major neurological abnormalities or diseases. * Has history of cancer (malignancy). * Has positive test(s) for Hepatitis B surface antigen (HBsAg), hepatitis C antibodies or human immunodeficiency virus (HIV).

Health status

Negative to : HIV, HBV, HCV, oncology

Study type

Interventional (clinical trial)

Enrollment

42

Allocation

Randomized

Intervention model

Cross-over assignment

Intervention model description

Not provided

Masking

Double-blind masking

Masking description

Not provided

Frequency of administration

Not provided

Studied LA-formulation(s)

Not provided

Studied route(s) of administration

Not provided

Use case

Not provided

Key resources

Not provided

MK-8527-010 -EXPrESSIVE-10

Identifier

NCT07071623

Link

https://clinicaltrials.gov/study/NCT07071623

Phase

Phase III

Status

Not yet recruiting

Sponsor

Merck Sharp & Dohme LLC

More details

Researchers are looking for new medicines to prevent HIV-1 (Human Immunodeficiency Virus Type 1) infection. The goals of this study are to learn: * If taking MK-8527 once a month works to prevent HIV-1 infection better than a standard (usual) pre-exposure prophylaxis (PrEP) taken once a day * About the safety of MK-8527 and if people tolerate it

Purpose

A Study of MK-8527 to Prevent Human Immunodeficiency Virus Type 1 (HIV-1) (MK-8527-010)

Interventions

Intervention 1

MK-8527

Dosage: 11 mg MK-8527 once monthly (QM)

Intervention 2

Placebo matched to MK-8527

Intervention 3

Emtricitabine/tenofovir disoproxil (FTC/TDF)

Dosage: once daily (QD)

Intervention 4

Placebo matched to FTC/TDF

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

2025-10-31

Actual Start Date

Not provided

Anticipated Date of Last Follow-up

2025-07-08

Estimated Primary Completion Date

2028-01-14

Estimated Completion Date

2028-01-14

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Children
- Adults

Genders

- Female

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: * Is confirmed Human Immunodeficiency Virus (HIV)-uninfected based on negative HIV-1/HIV-2 test results * Has been sexually active (2 vaginal intercourse encounters with cisgender male individual(s) within the last 3 months) * Was assigned female sex at birth and is cisgender. * Weighs ≥35 kg Exclusion Criteria: The main exclusion criteria include but are not limited to the following: * Has hypersensitivity or other contraindication to any component of the study interventions * Has evidence of acute or chronic hepatitis B infection * Has a history of malignancy within 5 years of screening except for adequately treated basal cell or squamous cell skin cancer, or in situ cervical cancer * Has t

Health status

Negative to : HIV, HBV
Other health status: 16 Years to 30 Years females

Study type

Interventional (clinical trial)

Enrollment

4580

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Quadruple-blind masking

Masking description

Not provided

Frequency of administration

Monthly

Studied LA-formulation(s)

Tablet

Studied route(s) of administration

Oral

Use case

PrEP

Key resources

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

Formulation patent families

Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
MK-8527 compound and analogues Expiry date: 2034-03-28 Provided is 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.	WO2015143712	Compound	Merck Sharp & Dohme Corp.	No	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted	Argentina, Brazil, China, Dominican Republic, Belarus, Azerbaijan, Armenia, Kazakhstan, Morocco, Albania, Serbia, Bosnia and Herzegovina, Montenegro, Türkiye, North Macedonia, Georgia, Jordan, Moldova, Republic of, Mexico, Malaysia, Peru, Philippines, El Salvador, Ukraine, South Africa, India, Namibia, Ghana, Botswana, Kenya, Colombia, Algeria, Honduras, Indonesia, Iran (Islamic Republic of), Lebanon, Mongolia, Nigeria, Pakistan, Tunisia, Venezuela (Bolivarian Republic of), Viet Nam	Australia, Canada, Chile, Costa Rica, Russian Federation, Liechtenstein, Italy, Norway, Malta, Denmark, Belgium, United Kingdom, Greece, Netherlands, Hungary, Croatia, Switzerland, Spain, Slovenia, Austria, Romania, Iceland, Cyprus, Finland, France, Bulgaria, Slovakia, Poland, Latvia, Ireland, Estonia, Germany, Luxembourg, Portugal, Czechia, Lithuania, Sweden, Israel, Japan, Korea, Republic of, New Zealand, Singapore, Taiwan, Province of China, United States of America, Gibraltar, Guyana, Panama, Seychelles, Trinidad and Tobago
Filed	World Intellectual Property Organization (WIPO), Argentina, Ecuador, Guatemala, Nicaragua, Belize, Egypt, Jamaica, Sri Lanka, Thailand	World Intellectual Property Organization (WIPO), Croatia, Barbados, Brunei Darussalam, Kuwait, United Arab Emirates, Bahrain, Saudi Arabia, Oman, Qatar

Patent status/countries	Low, Low- middle and upper-middle	High income
Not in force	World Intellectual Property Organization (WIPO), Tajikistan, Turkmenistan, Kyrgyzstan, Sierra Leone, Eswatini, Liberia, Sao Tome and Principe, Mozambique, Uganda, Zambia, Zimbabwe, Tanzania, United Republic of, Malawi, Rwanda, Sudan, Lesotho, Gambia (the)	World Intellectual Property Organization (WIPO), San Marino, Monaco, United States of America

Supporting material

Publications

There are no publication

Additional documents

- Discovery of MK-8527, a long-acting HIV nucleoside reverse transcriptase translocation inhibitor - Poster 638 - CROI2024
- Highlights of the 31st Conference on Retroviruses and Opportunistic Infections (CROI), March 3–6, 2024 Denver, Colorado, USA, March 2024Journal of Virus Eradication 10(1):100372 DOI:10.1016/j.jve.2024
- Weekly oral phrophylaxis with MK-8527 protects rhesus macaques from rectal challenge with SIV. HIVR4P 2024, 6–10 October 2024. Poster TUPE020.

Useful links

- Phase 1, open-label study to evaluate the drug interaction between MK-8527 and the oral contraceptive levonorgestrel/ethinyl estradiol in healthy adult females. IAS 2024
- Safety and Pharmacokinetics of MK-8527, a Novel nRTTI, in Adults Without HIV - (ABSTRACT 129 - CROI 2024) Gillian Gillespie, Merck & Co., Inc.,
- MK-8527 PK/PD Threshold and Phase 2 Dose Selection for Monthly Oral HIV-1 Preexposure Prophylaxis - CROI 2025
- CROI 2024: Pipeline ART – new drugs and formulations
- Single Dose Administration of MK-8527, a Novel nRTTI, in Adults With HIV-1 - Abstract 115 - CROI2024 -Russ Carstens, Merck & co.
- South African National Clinical Trials Registry
- MK-8527 PK/PD Threshold and Phase II Dose Selection for Monthly Oral HIV-1 Preexposure Prophylaxis - CROI2025- abstract 1232
- Single Dose Administration of MK-8527, a Novel nRTTI, in Adults With HIV-1
- AVAC trial entry
- Study Protocol
- Safety and Pharmacokinetics of MK-8527, a Novel nRTTI, in Adults Without HIV
- Safety and Pharmacokinetics of MK-8527, a Novel nRTTI, in Adults Without HIV
- Phase 1, open-label study to evaluate the drug interaction between MK-8527, an HIV-1 nucleoside reverse transcriptase translocation inhibitor, and the oral contraceptive levonorgestrel/ethinyl estradi
- In collaboration with the Gates Foundation, Merck advances MK-8527 pre-exposure prophylaxis (PrEP) clinical trials globally

Key results on Clinicaltrials.gov

- Clinical trial results of MK-8527-002 on clinicaltrials.gov

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

MK-8527 is an investigational nucleoside reverse transcriptase translocation inhibitor (NRTTI) being developed for the prevention of HIV as once-monthly oral capsule. It is prioritised by the Medicines Patent Pool (MPP) for public health oriented voluntary licensing since 2025. See more details here: https://medicinespatentpool.org/progress-achievements/prioritisation#pills-hiv